2013-1408
(Reexamination No. 95/000,565)

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MICHAEL J. VAILLANCOURT,

Appellant,

v.

BECTON DICKINSON & COMPANY,

Appellee.

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board

BRIEF OF BEHALF OF APPELLANT MICHAEL J. VAILLANCOURT

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 27(a)(7) and 47.4(a) counsel for Appellant Vaillancourt certifies the following:

1. The full name of every party or amicus represented by us is:

Michael J. Vaillancourt

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by us:

VLV Associates, Inc. a New Jersey Corporation.

3. All parent corporations and any publically held companies that own 10 percent or more of the stock of any party represented by us are:

None

4. The names of all law firms and the partners or associates that appeared for the parties now represented by us in the trial court or are expected to appear in this Court are:

Dennis F. Gleason
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Carella, Byrne, Cecchi, Olstein, Brody & Agnello, P.C.

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STATEMENT OF RELATED CASES

Michael J. Vaillancourt states that no other appeal from the same matter was previously before this Court or any other appellate court. The only litigation that Vaillancourt believes may be affected by this Court's decision is *VLV Associates v. Becton Dickinson & Company*, U.S. District Court for the District of New Jersey, Docket No. 12-2476(ES). That case has been administratively stayed/terminated on the consent of the parties.

STATEMENT OF JURISDICTION

This appeal arises from an *inter parties* reexamination proceeding before the U.S. Patent and Trademark Office ("PTO"). 35 U.S.C. §§311-14. Michael J. Vaillancourt, the patent owner, appealed from the examiner's rejection of all claims in the reexamination (including claims 1 to 20 of U.S. Patent No. 6,699,221 B2 and added claims 21 to 37) to the Board of Patent Appeals and Interferences (which is now known as the Patent Trial and Appeal Board) (collectively referred to as the "Board"), which had jurisdiction under 35 U.S.C. §§134(c) and 315(b)(1). The Board affirmed the examiner's rejection of claims 1 through 37 in a decision dated June 29, 2012. As of April 24, 2012, U.S. Patent No. 6,699,221 B2 was assigned to VLV Associates, Inc.; Vaillancourt, under authorization from the assignee, requested a rehearing, which the Board denied in a decision dated February

13, 2013. Vaillancourt under the same authorization appeals from those decisions. This Court has jurisdiction under 35 U.S.C. §141.

I. STATEMENT OF THE ISSUES

1. Did the Board err in affirming the examiner's rejection of claims 1 through 37 of U.S. Patent No. 6,699,221 B2 ("the '221 patent").
2. Did the Board err in its claim interpretation.
3. Did the Board err in the application of the facts in its interpretation of the claims of the '221 patent.
4. Did the Board's misapprehend the facts in its interpretation of the claims of the '221 patent as being readable on the applied prior art.
5. Did the Board misapprehend the facts in its interpretation of the claims of the '221 patent being unpatentable over the applied prior art.

II. STATEMENT OF THE CASE

This is an appeal by Michael Vaillancourt directed to U.S. Patent No. 6,699,221 B2 ("the '221 patent") issued March 2, 2004 which concerns a bloodless over the needle catheter. (A873-83.)

In August 2010, appellee Becton Dickinson & Company, ("B-D") as a third party requestor, filed for and was granted an *inter parties*

reexamination of the '221 patent. Claims 21 to 37 were added during the *inter parties* reexamination proceeding. (A884-89.)

As a result of the reexamination, the examiner rejected, on multiple grounds, claims 1 to 20 of the '221 patent and added claims 21 to 37 *i.e.* grounds numbered 1-9, 12-17, 20-28, 31-34, 36, 38 and 40-42. (A646-79.)

Vaillancourt appealed the examiner's rejections to the Board. (A680.)

The rejections of the examiner, for the most part, were affirmed (rejections 1-6, 14, 16, 17, 26, 36, 38 and 40-42) while others were reversed (rejection 5) or not addressed on the merits (rejections 7-13, 15, 20-25, 27, 28 and 33). (A766-806.)

Thereafter, Vaillancourt requested a rehearing by the Board. (A807-38.) Again the rulings of the examiner were affirmed. (A858-69.)

On appeal, the Board interpreted the claims of the '221 patent based on extrinsic evidence rather than on the intrinsic evidence provided in the '221 patent in an endeavor to 'read' the terms of the claims on the prior art. The Board concluded, based on its erroneous interpretation of the claims, that the claims were anticipated by and unpatentable over Cox as well as Luther; obvious over Van Huegten and Luther; and obvious over Vaillancourt '766. Because the conclusions of the Board are not sustainable as a matter of law, the decision of the Board should be reversed.

III. STATEMENT OF FACTS

A. Claim 1 Of The '221 Patent

The '221 patent contains 20 claims that were originally allowed over the prior art cited by the PTO without amendment. (A873-83.) Of these, claims 1, 19 and 20 are independent claims.

Claim 1 of the '221 patent reads as follows:

> A bloodless catheter comprising
> a first **hub** having a **bore** at a proximal end;
> a cannula fixed in and extending from an opposite distal end of said hub for invasive positioning in a blood vessel; and
> a **septum seal** mounted **in said bore of said hub in circumferentially sealed relation** to prevent a flow of fluid from said cannula to said proximal end of said hub, said seal having a weakened central section.

(Emphasis added).

B. The Intrinsic Evidence Of The '221 Patent

The written description of the specification in conjunction with the drawings of the '221 patent states:

"Various types of over-the-needle catheters have been known for use as venipuncture devices and, particularly, for intravenous infusion purposes. Typically, these devices have been fabricated of a needle that is connected to a hub and a catheter that passes over the needle and is fixed as by a friction fit at an exposed end of the needle. The catheter is also fixed to a hub that

receives the needle hub. Additional structure is also provided to form a closed chamber about the ends of the two hubs." (A879 [col. 1, lines 8-11].)

"U.S. Patent Nos. 5,330,435 and 5,234,410 describe different types of over-the-needle catheters which employ an elastomeric valve on a tube of the catheter to seal off the cannula of the catheter." (A879 [col. 1, lines 36-39].)

"U.S. Patent No. 5,211,634 describes a composite seal structure which is used in a coupling between a syringe and a line to a vein in a patient." (A879 [col. 1, lines 40-42].)

"U.S. Patent No. 5,487,728 describes the use of a seal having a resilient collapsible tubular portion and a septum at one end for sealing off a needle in a female luer connector." (A879 [col. 1, lines 43-45].)

"Accordingly, it is an object of the invention to provide product which would meet these needs and be substantially less complicated, less costly to make and assemble than the previously known products." (A879 [col. 1, lines 46-49].)

"Briefly, the invention is directed to a bloodless catheter comprised in part of a hub having a bore at a proximal end and a cannula fixed in and extending from an opposite distal end of the hub." (A879 [col. 1, lines 50-53].)

"In accordance with the invention, a septum seal with a weakened central section is mounted in the bore of the hub in circumferentially sealed relation to prevent a flow of fluid from the cannula to the proximal end of the hub." (A879 [col. 1, lines 54-57].)

"Typically, in order to form an over-the-needle catheter, a needle hub is telescopically mounted in the bore of the hub while an introducer needle is fixed in the needle hub and extends through the cannula. In use, the introducer needle and catheter are introduced into a patient in the usual manner. Thereafter, the introducer needle and associated hub are withdrawn. At this time, the seal closes on itself to seal off the cannula from the proximal end of the first hub so that blood cannot flow from the patient out of the hub." (A879 [col. 2, lines 19-27].)

"Fig. 1 [below] illustrates a cross-sectional view of a product constructed in accordance with the invention for use as an over-the-needle catheter." (A879 [col. 2, lines 32-34].)

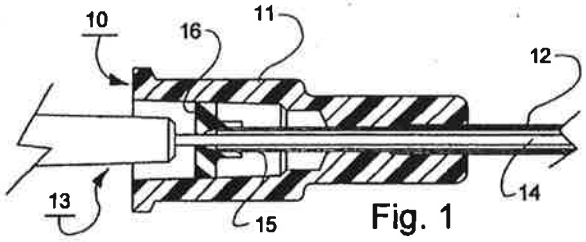


Fig. 1

"Fig. 3 [below] illustrates a view similar to FIG. 1 with the introducer needle removed." (A879 [col. 2, lines 34-36].)

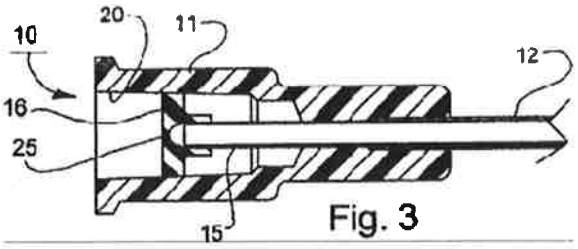


Fig. 3

"Fig. 4 [below] illustrates a view similar to FIG. 3 of the product connected to a male luer connector in accordance with the invention." (A879 [col. 2, lines 39-41].)

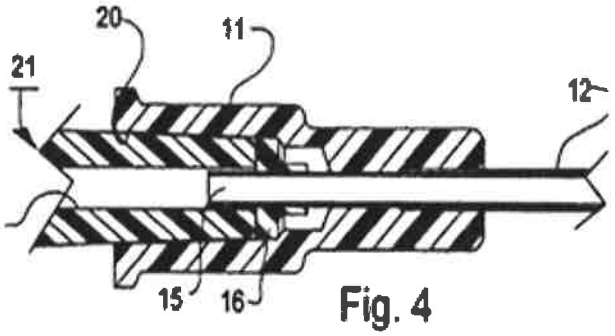


Fig. 4

"Referring to FIG. 1, the product 10 is constructed in the manner of an over-the-needle catheter with a hub 11, a cannula 12, *e.g.* a needle with a sharpened tip, made of metal or plastic, which is fixed in and which extends from the hub 11, a needle hub 13 and an introducer needle 14 which is fixed in the needle hub 13 and which extends coaxially through the cannula 12. The distal end of the needle 14 extends through the distal end of the cannula

12 and is secured thereto in a friction fit manner as is known. The construction of the hubs 11, 13, cannula 12 and needle 14 are conventional and need not be further described." (A880 [col. 3, lines 3-12].)

"The seal 16 is larger in diameter than the hub wall where the seal 16 is positioned is compressed thereby forming a pressure seal around the needle 14. In one example, the tube 15 has an outside diameter of 0.045", 'the tubular portion 17 of the seal 16 has an inner diameter of 0.037' and the cap 18 of the seal 16 has an outer diameter of 0.165" and a length of 0.040". In the sealed position, the hub wall where the seal 16 is positioned is of a diameter of 0.155". The compression on the seal 16 is thus 0.010" or approximately 6%. Under these conditions, the leakage pressure exceeds 10 psi." (A880 [col. 3, lines 32-40].)

"Referring to FIG. 1, the seal 16 is located in a recessed manner within a tapered bore 20 of the hub 11 and is disposed in a circumferentially sealed relation, *e.g.* in an interference fit manner to the bore 20 of the hub 11 to prevent a flow of fluid from the cannula 12 to the proximal end of the hub 11." (A880 [col. 3, lines 41-46].)

"The interference fit between the cap 18 of the seal 16 and the bore 20 of the catheter hub 11 determines the maximum pressure allowable in the

catheter 12 before leakage into the proximal end of the hub 11 occurs." (A880 [col. 3, lines 56-59].)

"Referring to FIG. 5, wherein like reference characters indicate like parts as above, the seal 16' is constructed as a simple 'septum' positioned at the entrance to the hub 11 (female luer adaptor). In this embodiment, the seal 16' is in the form of a disk having a tapered outer periphery, a weakened section defined by a coaxial recess 19' on one side to receive the tube 15' and a slit 23 centrally of the recess 19' to act as a valve." (A880 [col. 4, line 64-col. 5, line 4].)

"FIG. 13 illustrates an exploded view of the piercing ring of FIG. 12 with a modified seal with a duck bill configuration in accordance with the invention. ... FIG. 14 illustrates an exploded view of the piercing ring of FIG. 12 with another modified seal with a bullet configuration in accordance with the invention." (A879 [col. 2, lines 62-67].)

C. The Decision Of The Board

The Board stated that the meaning of "[t]he limitation 'mounted in said bore of said hub in circumferentially sealed relation' is in dispute." (A772.)

The Board further concluded:

a. The term "hub" commonly is a base by which a needle is attached to a device (citing to www.merriam-webster.com). (A785-86.)

b. The term "bore" is not defined in the '221 patent, and the Board elected not to limit the meaning to the particular examples in the '221 patent. (A774.)

c. The term "bore" generally means a hollow chamber or barrel or the inner surface thereof that is "usually" cylindrical (citing to www.thefreedictionary.com). (A774.)

d. Thus, a "bore" need not necessarily be cylindrical and recesses formed within a hollow chamber or barrel are not precluded from constituting a portion of the "bore." (A774-75.) However, the Board cites to no evidence to support the conclusion that recesses formed within a hollow chamber or barrel are not precluded from constituting a portion of the "bore".

e. "On its face, the phrase ["circumferentially sealed relation"] means that the septum and the bore are related such that a seal is formed around a circumference of the seal." (A775.)

f. The ordinary meaning of the word "mounted" is placed or fixed on or in an appropriate support, or, more generally, "supported" (citing to www.thefreedictionary.com). (A774.)

The Board couched the issue before it as: "Under a proper interpretation of the language of claim 1, does the evidence support the [e]xaminer finding that Vaillancourt '766 describes 'a septum seal mounted in said bore of said hub in a circumferentially sealed relation'?" (A798.)

The Board further concluded:

a. The term "septum seal" is also not expressly defined in the '221 patent. (A799.)

b. "The term 'septum' commonly means 'a dividing wall separating two spaces'" citing to http://www.merriam-webster.com/medical/septum, accessed June 24, 2012 ("a dividing wall or membrane especially between bodily spaces or masses of soft tissue"). (A799.)

IV. SUMMARY OF ARGUMENT

As a fundamental flaw, contrary to law, the Board erred by basing its claim interpretation on extrinsic evidence.

The Board did not rely upon the terms of the claims or on the intrinsic evidence provided by the specification and drawings of the '221 patent but instead grounded its ruling on extrinsic evidence.

The Board compounded its error in its interpretation of the claims of the '221 patent as being readable on and unpatentable over the applied prior art.

V. ARGUMENT

As a matter of law, the Board erred in its claim interpretation. Rather than grounding the interpretation of the terms "hub," "bore" and "septum seal" and the phrase "circumferentially sealed relation" on the intrinsic evidence in the '221 patent, the Board based its claim interpretation on extrinsic evidence.

A. Standards Of Review

1. Claim construction is a purely legal question and is reviewed *de novo*

This Court reviews "claim construction *de novo* on appeal including any allegedly fact-based questions relating to claim construction." *Cybor Corp. v. FAS Technologies, Inc.* 138 F.3d 709, 714 (Fed. Cir. 1998).

2. Factual findings of the Board are reviewed for substantial evidence based on the entire closed record

This Court reviews factual findings of the Board for substantial evidence that is "confined to the factual record compiled by the Board." *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000). "Under the substantial evidence standard of review, [the Court] search[es] for evidence, clearly set forth in the record below, to justify the conclusions that the Board has drawn." *Brand v. Miller,* 487 F.3d 862, 868 (Fed. Cir. 2007).

As explained in *Gartside:*

> In appeals from the Board, we have before us a comprehensive record that contains the arguments and evidence presented by the parties, including all of the relevant information upon which the Board relied in rendering its decision. That record, when before us, is closed, in that the Board's decision must be justified within the four corners of that record.

Id., 203 F.3d at 1514 (internal citation omitted). This Court has also "expressly held that the Board's opinion must explicate its factual conclusions, enabling [the Court] to verify readily whether those conclusions are indeed supported by 'substantial evidence' contained within the record." *Id.* (citing *Gechter v. Davidson,* 116 F.3d 1454, 1460 (Fed. Cir. 1997).)

3. The Board must ground it ruling on concrete evidence

This Court has made clear that in determining patentability, the Board cannot simply rely on "common sense" or its own expertise; it must point to specific factual support:

> As an administrative tribunal, the Board clearly has expertise in the subject matter over which it exercises jurisdiction. This expertise may provide sufficient support for conclusions as to peripheral issues. With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience—or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings. To hold otherwise would render the process of appellate review for substantial evidence on the record a meaningless exercise.

In re Zurko, 258 F.3d 1379, 1385-86 (Fed. Cir. 2001) (citing *Baltimore & Ohio R.R. Co. v. Aderdeen & Rockfish R.R. Co.,* 393 U.S. 87, 91-92 (1968)); *accord Brand,* 487 F.3d at 869 ("[I]n the context of a contested case, it is impermissible for the Board to base its factual findings on its expertise, rather than on evidence in the record, although the Board's expertise appropriately plays a role in interpreting record evidence.").

4. The Board's ultimate conclusion of obviousness is reviewed *de novo*

"Obviousness is a question of law that [this Court] review[s] *de novo* with underlying factual findings." *In re NTP, Inc.,* 654 F.3d 1279, 1297 (Fed. Cir. 2011); *see also In re ICON Health & Fitness, Inc.,* 496 F.3d 1374, 1378 (Fed. Cir. 2007) ("Although based on determinations of underlying facts, which we review for substantial evidence, the ultimate conclusion of obviousness is a legal question, which we review *de novo*.").

The key to supporting any rejection under 35 U.S.C. §103 is the clear articulation of the reasons why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex, Inc.,* 550 U.S. 398 (2007) noted that the analysis supporting a rejection under 35 U.S.C. §103 should be made explicit. The Court, quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'"

For a *prima facie* case of obviousness to exist, there must be "some objective teaching in the prior art or . . . knowledge generally available to one of ordinary skill in the art [that] would lead that individual to combine the relevant teachings of the references." *In re Fine,* 837

F.2d 1071, 1074 (Fed. Cir. 1988). "The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved." *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000).

Rejections based on §103(a) must rest on a factual basis with these facts being interpreted without hindsight reconstruction of the invention from the prior art. *See In re Warner,* 379 F.2d 1011, 1017 (CCPA 1967).

B. The Board erred in affirming the examiner's rejection of claims 1 to 37 based on extrinsic evidence rather than on the intrinsic evidence of the '221 patent

In interpreting a claim, a court must first "look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d 1576, 1581 (Fed. Cir. 1996).

Claim 1 requires "a first hub having a bore at a proximal end" as well as "a septum seal mounted in said bore of said hub in circumferentially sealed relation." (A882 [col. 7, line 35].)

During examination, claims are given their broadest reasonable construction that is consistent with the specification. *In re Hyatt,* 211 F.3d 1367, 1372 (Fed. Cir. 2000). A limitation may not be read into a claim from

the specification, but it is appropriate to look to the specification to define a limitation already in the claim. *Elekta Instr. S.A. v. O.U.R. Sci. Intl, Inc.,* 214 F.3d 1302, 1307 (Fed. Cir. 2000).

The written description of the '221 patent describes the hub 11 and the bore 20 and Figures 1, 3 and 4 illustrate the hub 11 and the bore 20. There is no ambiguity as to the meaning of the terms "hub" and "bore" in claim 1 that would require an interpretation based on extrinsic evidence.

The written description of the '221 patent describes a seal 16 mounted in the bore 20 of the hub 11 in circumferentially sealed relation and figures 1, 3 and 4 illustrate the seal 16 mounted in the bore 20 of the hub 11.

The written description of the '221 patent describes a second embodiment of a seal (16'; figure 5) constructed as a simple "septum" ("the seal 16' is in the form of a disk having a tapered outer periphery"). (A880 [col. 4, lines 64-67 to col. 5, lines 1-6].)

The written description of the '221 patent describes and the drawings illustrate a modified seal with a duck bill configuration and another modified seal with a bullet configuration.

There is no ambiguity as to the meaning of the term "septum seal" in claim 1 that would require an interpretation based on extrinsic evidence.

MPEP §2111.01 requires that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989); *Chef America, Inc. v. Lamb-Weston, Inc.,* 358 F.3d 1371, 1372 (Fed. Cir. 2004).

"[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*); *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 (Fed. Cir. 2003).

Extrinsic evidence may be relied upon only when intrinsic evidence cannot resolve the ambiguity of a disputed claim. See *Vitronics*, 90 F.3d at 1583.

Based upon the Board's errors in relying upon extrinsic evidence rather than upon the intrinsic evidence of the '221 patent and not properly applying the law of claim interpretation, the examiner's rejection of claims 1 through 37 should be reversed.

C. The Board Improvidently Relied On Extrinsic Evidence Although The Intrinsic Evidence Provided Sufficient Basis To Interpret The Claims

1. Claims 1-3, 6, 23 and 25 are not anticipated by Cox

The Board erred in affirming the examiner's finding that claims 1-3, 6, 23 and 25 are anticipated by Cox. (A775-79.)

> A person shall be entitled to a patent unless .... the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

35 U.S.C. §102(b).

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *Verdegaal Bros. v. Union Oil Co.,* 814 F.2d 628, 631 (Fed. Cir. 1987).

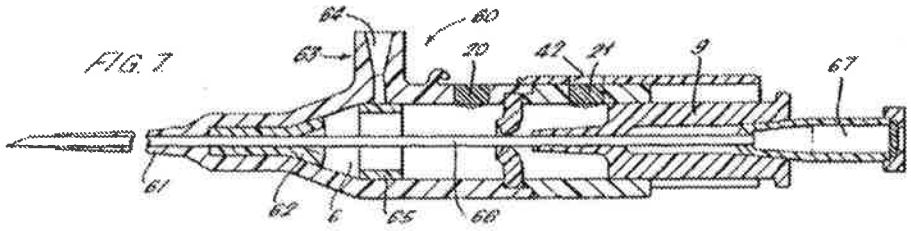
In order to anticipate, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989).

As held in *Net MoneyIN Inc. v. VeriSign Inc.,* 545 F.3d 1359 (Fed. Cir. 2008)

> To anticipate a claim, a single prior art reference must expressly or inherently disclose each claim limitation.... But disclosure of each element is not quite enough—this court has long held that '[a]nticipation requires

> the presence in a single prior art disclosure of all elements of a claimed invention *arranged as in the claim.'"* [citing *Finisar Corp. v. DirecTV Group, Inc., 523* F.3d 1323 at 1334] (quoting *Connell,* 722 F.2d at 1548). In all of these cases, the prior art reference had to show the claimed invention arranged or combined in the same way as recited in the claim in order to anticipate. We thus hold that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. §102.

Figure 7 of Cox depicts a sectional view of a device for use in intravenous infusion into a catheter via a cannula 61 that is integrally formed with a housing (not labeled in Figure 7). (A776.)



The Board stated "we see no reason to conclude that the phrase 'fixed in and extending from' would necessarily require that the cannula and the hub be 'separate' as suggested by Vaillancourt. The term 'fixed' commonly means 'secured in place or fastened'" (citing to www.merriam-webster.com). (A777.) The Board continued: "We decline to strictly limit

the scope of the claims to the embodiments in the figure of the '221 patent," citing *Phillips,* 415 F.3d at 1323.

a. Claim 1

Claim 1 requires both "a hub" and "a cannula," *i.e.* two separate elements. Thus, the fact that Cox's catheter has "a cannula formed integrally with the housing 2 and communicating with the first chamber" means that Cox does not anticipate the structure of claim contrary to the Board's conclusion. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson,* 868 F.2d at 1236. For this reason alone, the rejection of claim 1 as anticipated by Cox (rejections 1 and 31) is not warranted pursuant to the provisions of 35 U.S.C. §102.

Further, the Board concluding that the term "fixed" commonly means "secured in place or fastened" supports the requirement of claim 1 that "a hub" and "a cannula" be two separate elements. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *See Phillips,* 415 F.3d at 1313.

The Board also erroneously concluded that Cox discloses "a septum seal 'mounted in said bore of said hub.'" (A777.)

The Board continued "Based on the claim interpretation [adopted from the examiner], the phrase 'mounted in said bore of said hub' does not preclude the septum seal from being … disposed in a recess that defines a portion of a bore." (A774-75.)

The Board does not cite to any evidence to support its reasoning that "recesses formed within a hollow chamber or barrel are not precluded from constituting a portion of the "bore."' (A777-78.)

The Board mistakenly posited that the term "bore" is not defined in the '221 patent. (A774.)

The term "bore," in fact, is defined in the written description of the invention in compliance with the requirements of 35 U.S.C. §112. That is, the seal 16 is located in a recessed manner within a tapered bore 20 of the hub 11 and is disposed in a circumferentially sealed relation, *e.g.* in an interference fit manner to the bore 20 of the hub 11 to prevent a flow of fluid from the cannula 12 to the proximal end of the hub 11. (A880 [col. 3, lines 41-46].)

Further, as a matter of fact, the written description states "Referring to FIG. 1, the product 10 is constructed in the manner of an over-the-needle catheter." (A880 [col. 3, lines 3-12].)

The written description states "Typically, in order to form an over-the-needle catheter, a needle hub is telescopically mounted in the bore of the hub while an introducer needle is fixed in the needle hub and extends through the cannula." (A879 [col. 2, lines 54-57].) There is no description that the "bore" of claim 1 would mean a bore other than the bore 20 of Figure 1 to a person of ordinary skill in the art.

Plainly, figure 1 defines the term "bore" by illustrating the "bore" in compliance with the requirements of 35 U.S.C. §113.

In interpreting a claim, a court must first "look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." *Vitronics,* 90 F.3d at 1581.

What is more, MPEP §2111.01 requires that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz,* 893 F.2d at 321; *Chef America* 358 F.3d at 1372.

The Board has not provided a reasonable interpretation of the terms of claim 1 consistent with the specification but instead relies on extrinsic evidence to formulate unreasonable interpretations of the claim terms.

When considering a claim, the skilled person should rule out interpretations which are illogical or which do not make technical sense.

That person should arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure and be construed by a mind willing to understand, not to a mind desirous of misunderstanding.

As illustrated in figure 7 of Cox, the seal is not mounted in a "bore" of a housing but in a recess at the end of one housing part and is retained therein by a second telescopic housing part. (A876.)

For these additional reasons, the rejection of claim 1 as anticipated by Cox (rejections 1 and 31) is not warranted pursuant to the provisions of 35 U.S.C. §102 and the rejection by the examiner should be reversed.

b. Claim 23

Claim 23 depends from claim 1 and further requires that the "seal is sealed in an interference fit manner to said bore of said hub, said interference fit determining the maximum pressure allowable in said catheter before leakage into said proximal end of said hub occurs." (A887-88.)

The Board agreed that Cox does not expressly disclose a relationship between the "force fit" of the membrane and the maximum pressure allowable before leakage. (A778.)

However, the Board continued that "Cox teaches that the radial compression of the membrane 4 is what prevents blood from leaking from

the distal first chamber 6 to the second proximal chamber 7. We agree with the [e]xaminer that the interference fit taught by Cox necessarily dictates the maximum pressure at which blood would leak around the membrane 4." (A779.)

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993); *In re Oelrich,* 666 F.2d 578, 581-82 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" "*In re Robertson,* 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted).

Here, neither the examiner nor the Board provided any extrinsic evidence to make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill.

In fact, the Board's opinion that the interference fit taught by Cox necessarily dictates the maximum pressure at which blood would leak

around the membrane 4 is contrary to the teaching of Cox. Since Cox teaches that the membrane 4 has a central zone of weakness 22 comprising a cruciform cut measuring 3 mm in each direction with a membrane thickness of 2mm (A913 [col. 4, lines 23-27].), the radial compression of the membrane 4 is what prevents blood from leaking from the distal first chamber 6 to the second proximal chamber 7 *through the cruciform cut*. There can be no leakage of blood *around* the membrane 4 since the membrane 4 is accommodated in an annular recess 5.

For the above reasons, the rejection of claim 23 as anticipated by Cox is not warranted pursuant to the provisions of 35 U.S.C. §102 and should be reversed.

As claims 2, 3, 6, 23 and 25 depend from claim 1 and were rejected for the same reasons, they, too, should stand.

2. Claims 1-3, 6, 22, 23 and 25 are <u>not</u> obvious over the teachings of Cox

The Board erred in affirming the examiner's finding that claims 1-3, 6, 22, 23 and 25 are obvious over the teachings of Cox. (A779.)

The Board did not supply its reasoning as to the merits based on the Board's affirmation of the Examiner's anticipation rejection merely stating "that lack of novelty is the ultimate or epitome of obviousness." (A779.)

For the reasons set forth in above, the rejection of claims 1-3, 6, 22, 23 and 25 as obvious over the teachings of Cox (rejections 2 and 30) is not warranted pursuant to the provisions of 35 U.S.C. §103 and should be reversed.

Of note, claim 22 was not rejected as anticipated by Cox. Claim 22 depends from claim 1 and requires the seal of claim 1 to be "larger in diameter than said hub bore where said seal is positioned to provide a leakage pressure exceeding 10 psi." (A887.)

3. Claims 1-3, 6, 16, 24 and 26 are <u>not</u> obvious based on Cox and Sylvanowicz

The Board erred in affirming the examiner's finding that claims 1-3, 6, 16, 24 and 26 are obvious based on Cox and Sylvanowicz. (A780-82.)

The Board affirmed the examiner's conclusion that it would have been obvious for one of ordinary skill in the art to have combined the central aperture of the seal of Sylvanowicz with the device and membrane of Cox to meet the limitation of a seal with a weakened section. (A781.)

However, combining the seal of Sylvanowicz with the device and membrane of Cox would not result in the structure of claim 1. For the reasons set forth above with respect to the meaning of the terms of claim 1, the rejection of claims 1-3, 6, 16, 24 and 25 as obvious based on Cox and

Sylvanowicz (rejections 2 and 30) is not warranted pursuant to the provisions of 35 U.S.C. §103 and should be reversed.

4. Claim 17 is not obvious based on Cox and Fischell

The Board erred in affirming the examiner's finding that claim 17 is obvious based on Cox and Fischell. (A782.)

Claim 17 depends from claim 1 and further recites "a stylet extending through said weakened section of said seal and said cannula." (A882 [col. 8, lines 27-30].)

The Board noted that the examiner found that "it would have been obvious to use a stylet with the catheter of Cox …." (A782.)

However, using a stylet with the catheter of Cox would not result in the structure of claim 1. For the reasons set forth above with respect to the meaning of the terms of claim 1, the rejection of claim 17 as obvious based on Cox and Fischell (rejection 4) is not warranted pursuant to the provisions of 35 U.S.C. §103 and should be reversed.

5. Claims 1, 3, 6, 10-14 and 18 are not anticipated by or obvious over the teachings of Luther

The Board erred in affirming the examiner's finding that claims 1, 3, 6, 10-14 and 18 are anticipated by and are obvious over the teachings of Luther. (A783.)

The Board reproduced Figure 3 of Luther and stated:

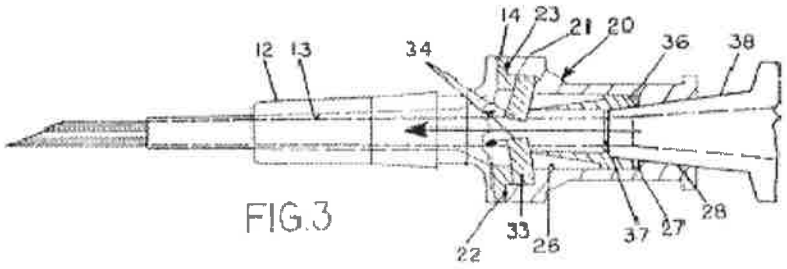


FIG.3

"Figure 3 of Luther is a sectional side elevation view of a connector device having a septum seal 33 for providing a sterile closure for use with I.V. and syringe systems, with the septum portion being open for liquid flow." (A784.)

The examiner found that septum 33 is "mounted in said bore of said hub in circumferentially sealed relation." (A784.)

The Board went on to conclude "Based on the claim interpretation discussed [in the decision], the phrase 'mounted in said bore of said hub' does not preclude the septum from being permanently fixed or disposed in a recess that defines a portion of a bore." (A785.)

As with the structure illustrated in figure 7 of Cox, the septum 33 of Luther is not mounted in a "bore" of a housing but instead is mounted in a recess at the end of one fitting 20 and retained in place by a second telescopic fitting 11. (A876.)

In fact, Luther discloses "A space 32 is formed between the faces 17 and 25, respectively of the proximal fitting 11 and distal fitting 20, and a resilient septum 33 is fitted into this space." (A939 [col. 2, lines 18-20].)

As a matter of law, in order to anticipate, "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson,* 868 F.2d at 1236.

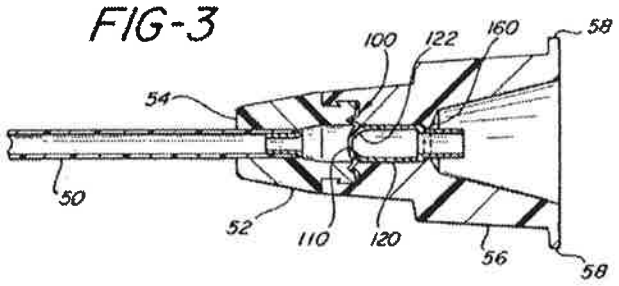
For reasons as set forth above with respect to the meaning of the terms of claim 1, the rejections of claims 1, 3, 6, 10-14 and 18 (rejections 5 and 6) as anticipated by and as obvious over the teachings of Luther are not warranted pursuant to the provisions of 35 U.S.C. §102 and §103 and should be reversed.

6. Claims 1-3, 6, 10-15 and 20 are <u>not</u> obvious over the teachings of Van Heugten and Luther

The Board erred in affirming the examiner's finding that claims 1-3, 6, 10-15 and 20 are obvious over the teachings of Van Heugten and Luther. (A787.)

The Board stated "Figure 3 of Van Huegten [reproduced below] depicts a detailed cross sectional view of a catheter assembly having a catheter 50 and a catheter hub 52 incorporated with a membrane assembly

100 comprising a one-directional valve membrane 110." (A788.)



The Board went on to affirm the examiner's finding that Van Huegten describes "a septum seal mounted in said bore of said hub in a circumferentially sealed relation." (A788.) Further, the Board stated: "Based on the claim interpretation discussed [in the decision], the phrase 'mounted in said bore of said hub' does not preclude the septum seal from being permanently fixed, disposed in a recess that defines a portion of a bore, or sandwiched between two pieces that define a hub."

a. Claim 1

Because the Board erred in basing its claim interpretation on extrinsic evidence, the examiner's finding that Van Huegten describes "a septum seal mounted in said bore of said hub in a circumferentially sealed relation" should be reversed.

As with the structure illustrated in figure 7 of Cox, the valve membrane 110 of Van Huegten is not mounted in a "bore" of a housing but

instead is mounted in a recess at the end of one element 56 and retained in place by a second element 52.

Further, modifying the membrane 110 of Van Huegten with the weakened central section of Luther would not result in the structure of claim 1.

For reasons as set forth above with respect to the meaning of the terms of claim 1, the rejection of claims 1, 3, 6 and 10-15 (rejection 14) as obvious over Van Huegten and Luther is not warranted pursuant to the provisions of 35 U.S.C. §103 and should be reversed.

b. Claim 20

Claim 20 is an independent claim directed to a combination that requires, *inter alia*, "a septum seal mounted in said bore of said hub in circumferentially sealed relation, said seal having a centrally disposed slit to define a valve, and a piercing ring mounted on said seal concentrically of said slit" and "a male luer adaptor … sized to engage and push said piercing ring through said slit in said seal to communicate said adaptor with said cannula". (A882 [col. 8, lines 49-64.)

Van Heugten discloses:

> As is further seen in FIGS. 3 and 4c, hub 52 also contains membrane opener 120. Membrane opener 120 is generally cylindrical in shape and contains nose-shaped opening means

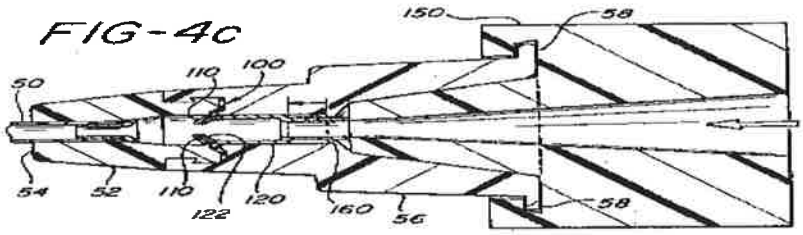
> 122. These nose shaped opening means 122 fit comfortably within valve membrane 110 when so inserted."

(A946 [col. 4, lines 31-36].)

***

> As luer assembly 150 is being attached to catheter hub 52, collar mechanism 160 holds membrane opener 120 in place so that nose-shaped opening means 122 of membrane opener 120 proceed to open valve membrane 110. This is best seen in FIG. 4c. Thus, when the valve membrane 110 is open, nutritional fluids are able to be disposed into the body.

(A946 [col. 4, lines 43-49].)



As shown in figure 4c of Van Huegten above, the membrane opener 120 is not pushed through the opening formed in the membrane 110. (A944.)

For reasons as set forth above with respect to the meaning of the terms of claim 1, the rejection of claim 20 (rejection 14) as obvious over

Van Huegten and Luther is not warranted pursuant to the provisions of 35 U.S.C. §103 and should be reversed.

7. Claims 21 and 33 are not obvious over Van Heugten in view of Luther and Vaillancourt '728

The Board erred in affirming the examiner's finding that claims 21 and 33 are obvious over Van Heugten in view of Luther and Vaillancourt '728. (A794.)

Claim 21 depends from claim 1 and claim 33 depends from claim 20. For reasons as set forth above with respect to claims 1 and 20, the rejection of claims 21 and 33 (rejection 26) as obvious over Van Huegten, Luther and Vaillancourt '728 is not warranted pursuant to the provisions of 35 U.S.C. §103 and should be reversed.

8. Claims 34 and 36 are not obvious over Van Heugten in view of Luther and Cox

The Board erred in affirming the examiner's finding that claims 34 and 36 are obvious over Van Heugten in view of Luther and Cox. (A795-96.)

a. Claim 34

Claim 34 depends from independent claim 20 and further requires the seal of claim 20 to be "sealed in an interference fit manner to said bore of said hub, said interference fit determining the maximum pressure allowable

in said catheter before leakage into said proximal end of said hub occurs." (A889.)

For the reasons set forth above with respect to claim 23, the rejection of claim 34 as obvious over Van Heugten in view of Luther and Cox is not warranted pursuant to the provisions of 35 U.S.C. §103 and should be reversed.

Further, as described, the membrane 110 of Van Heugten is mounted in a recess at the end of one element 56 and retained in place by a second element 52. Neither the examiner nor the Board has provided any evidence as to how the membrane 110 can be modified by applying radial compression thereon or a clear articulation of the reason why this would have been obvious.

Still further, neither the examiner nor the Board has provided any reasoning as to why one of ordinary skill in the art would modify the mounting of the membrane 110 of Van Heugten (that requires the membrane to be mounted in a recess at the end of one element 56 and retained in place by a second element 52) by mounting the membrane 110 with a friction fit in the recess at the end of the element 56 and then retain the compressed membrane in place by the second element 52. Since there is no opening in

the membrane 110 when mounted in place, radial compression is not required to close any opening.

9. Claim 35 is not obvious over Van Heugten in view of Luther and Sylvanowicz

The Board erred in affirming the examiner's finding that claim 35 is obvious over Van Heugten in view of Luther and Sylvanowicz. (A796.)

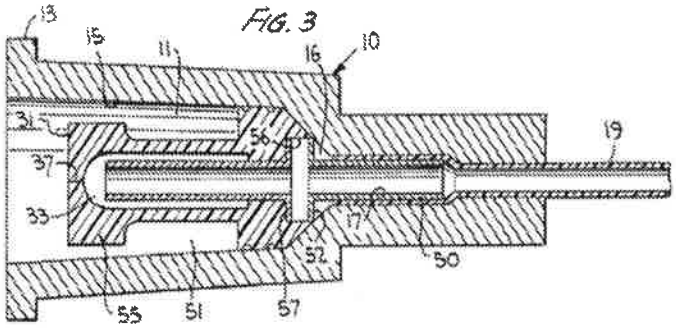
Claim 35 depends from claim 20. For reasons as set forth above with respect to claim 20, the rejection of claim 5 (rejection 41) as obvious over Van Huegten, Luther and Sylvanowicz is not warranted pursuant to the provisions of 35 U.S.C. §103 and should be reversed.

10. Claims 1-4, 6-9, 15, 19 and 27-30 are not obvious over Vaillancourt '766

The Board erred in affirming the examiner's finding that claims 1-4, 6-9, 15, 19 and 27-30 are obvious over Vaillancourt '766. (A797-805.)

The Board stated "Figure 3 of Vaillancourt '766 depicts a sectional view of a catheter assembly having a valve member 55 with an outwardly extending annular flange 52 that engages the wall in chamber 16 in an

interference fit. (Vaillancourt '766, [A952] col. 3, [lines] 32-33 and col. 6, lines 51-68.)"



The Board further stated "The issue before us is: Under a proper interpretation of the language of claim 1, does the evidence support the [e]xaminer's finding that Vaillancourt '766 describes 'a septum seal mounted in a bore of said hub in a circumferentially sealed relation'? We answer this question in the affirmative." (A798.)

The Board erroneously concluded "The term 'septum seal' is not expressly defined in the '221 patent.... We are not persuaded that the [s]pecification of the '221 patent excludes a seal of the shape described in Vaillancourt '766...." (A798-99.)

a. Claim 1

As a matter of fact, the term "septum" is defined in the written description of the invention in compliance with the requirements of 35 U.S.C. §112. (A879 [col. 2, lines 32-36, 39-41, 62-67; col. 3, lines 32-46, 56-59; col. 4, line 64 to col. 5, line 4].). That is, the seal 16 is located in a

recessed manner within a tapered bore 20 of the hub 11 and is disposed in a circumferentially sealed relation, *e.g.* in an interference fit manner to the bore 20 of the hub 11 to prevent a flow of fluid from the cannula 12 to the proximal end of the hub 11.

Vaillancourt '766 discloses a valve member 55 having an enlarged support end contacting a chamber wall 15 in a friction fit (A953 [col. 6, lines 62-64].) and an axially collapsible thin-walled section 54 existing between the thicker end sections of the valve member. (A953 [col. 7, lines 1-3].)

The Board erroneously concluded: "Based on the claim interpretation discussed [in the decision], the phrase 'mounted in said bore of said hub' does not preclude the septum seal from being supported circumferentially at one end and extended freely into space at the other end." (A799.)

One of ordinary skill in the art would not interpret the "septum seal" of claim 1 to read on the valve member 55 of Vaillancourt '766 that is formed of an enlarged support end 52, a thin-walled section 54 and flat circular end 31. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips,* 415 F. 3d at 1313.

Certainly, in view of the description of the '221 patent regarding the several embodiments of a septum seal including the simple septum seal 16' of figure 5 (A880-81 [col. 4, line 64 - col. 5, line 4]), one of ordinary skill in the art would not interpret the "septum seal" of claim 1 to read on the valve member 55 of Vaillancourt '766.

Further, the '221 patent distinguishes the use of **a seal having a resilient collapsible tubular portion and a septum at one end** for sealing off a needle in a female luer connector as described in Vaillancourt '728 from the septum seal of the invention. (A879 [col. 1, lines 43-49].)

Vaillancourt '728 illustrates a female luer connector in figure 1:

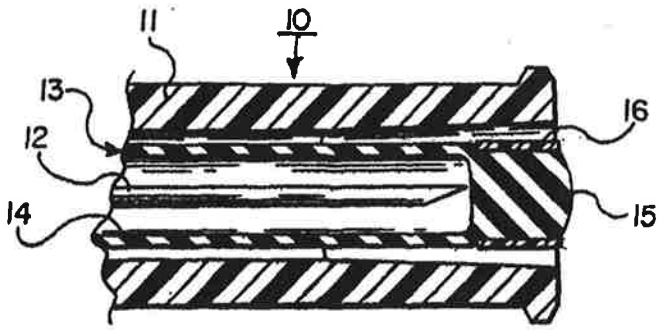


Fig 1

The structure of Vaillancourt '728 is described as a female luer connector 10 including a rigid tubular portion 11, for example, made of plastic, a hollow needle 12, for example, a stainless steel 20 gauge needle fixedly mounted within and relative to the plastic tubular portion 10 and a tubular shield or boot 13 mounted over the needle 12. The tubular shield 13

is made, for example, of rubber, and includes a resilient collapsible tubular portion or sleeve 14 which is concentric to the needle 12 and a septum 15 at the distal end of the collapsible tubular portion 14 which is disposed in facing spaced relation to the needle 12. (A952 [col. 3, lines 29-39].).

The '221 patent distinguishes the septum seal of the invention from the tubular shield 13 of Vaillancourt '728 and, by analogy, distinguishes the septum seal of the invention from the valve as described in Vaillancourt '766 having a resilient collapsible tubular portion 54 and a septum (31) at one end for sealing off a needle in a female luer connector. Thus, contrary to the holding of the Board (that the valve member 55 of Vaillancourt '766 is a septum seal mounted in a bore of said hub in a circumferentially sealed relation), the specification of the '221 patent excludes a seal of the shape described in Vaillancourt '766. A limitation may not be read into a claim from the specification, but it is appropriate to look to the specification to define a limitation already in the claim. *Elekta*, 214 F.3d at 1307.

Both as a matter of law and fact, the phrase "mounted in said bore of said hub" does preclude the septum seal from being supported circumferentially at one end and extended freely into space at the other end. This is particularly so when reading the phrase in the full context of the claim, *i.e.* "mounted in said bore of said hub in circumferentially sealed

relation." In interpreting a claim, a court must first "look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." *Vitronics,* 90 F.3d at 1581.

As stated in the '221 patent, the object of the invention is to provide product which would be substantially less complicated, less costly to make and assemble than the previously known products. (A879 [col. 2, lines 46-49].)

The Board cites to no evidence to support the examiner's finding that Vaillancourt '766 describes "a septum seal mounted in a bore of said hub in a circumferentially sealed relation." On the other hand, for the reasons set forth above, the '221 patent provides evidence to support a finding that Vaillancourt '766 does not describe "a septum seal mounted in a bore of said hub in a circumferentially sealed relation."

Based on the intrinsic evidence of the '221 patent referenced above, the examiner's finding that that claim 1 of the '221 patent reads on the device structure described in Vaillancourt '766 is in error.

For reasons as set forth above with respect to the meaning of the terms of claim 1, the rejection of claims 1, 6-9, 15 and 27 (rejections 5 and 6) as obvious over Vaillancourt '766 is not warranted pursuant to the provisions of 35 U.S.C. §103 and should be reversed.

b. Claim 4

Claim 4 depends from claim 1 and requires the seal of claim 1 to be "slidably mounted in said bore." (A882 [col. 7, lines 48-49].)

The Board held "the [e]xaminer finds the mounting and axial movement of valve member 55, as a whole, meets the requirements of claim 4. Accordingly, we are unconvinced that the [e]xaminer's position, which is based on sufficient rational underpinnings, is improper." (A801.)

A position "based on sufficient rational underpinnings" is not supported as a matter of law. See *Vitronics,* 90 F.3d at 1581.

Further, a finding that the mounting and axial movement of valve member 55 of Vaillancourt '766, as a whole, belies the facts. First, as a whole, the valve member 55 of Vaillancourt '766 is formed of an enlarged support end 52, a thin-walled section 54 and flat circular end 31. As a whole, the valve member 55 is fixed against the chamber wall 15 in a friction fit. (A953 [col. 6, lines 62-66].). Second, as a whole, the valve member 55 collapses axially. (A953 [col. 6, lines 68-col. 7, line 3].) Thus, the valve member 55, as a whole, is not "slidably mounted" in the bore of the hub 10. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the

time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips,* 415 F. 3d at 1313.

For these additional reasons, the rejection of claim 4 (rejections 5 and 6) as obvious over Vaillancourt '766 is not warranted pursuant to the provisions of 35 U.S.C. §103 and should be reversed.

c. Claim 19

Independent claim 19 is directed to a combination that requires, as claim 1, a "first hub having a bore at a proximal end, a cannula fixed in and extending from an opposite distal end of said hub, a septum seal mounted in said bore of said hub in circumferentially sealed relation to prevent a flow of fluid from said cannula to said proximal end of said hub" as well as "a tube mounted in said seal in sealed relation and extending into said cannula." (A882 [col 8, lines 33-48].)

For reasons as set forth above with respect to claim 1, the rejection of claims 19 and 28-30 (rejections 5 and 6) as obvious over Vaillancourt '766 is not warranted pursuant to the provisions of 35 U.S.C. §103 and should be reversed.

VI. CONCLUSION

For the reasons stated more fully above, this Court should reverse the Board's affirming the examiner's rejections of claim 1-37 in the *inter partes* reexamination of U. S. Patent No. 6,699,221 B2, issued March 2, 2004.

Respectfully submitted,

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July 15, 2013

CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief contains 9,103 words as measured by the word processing software used to prepare this brief.

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CERTIFICATE OF SERVICE

I certify that on July 15, 2013, the foregoing brief was filed by way of the Court's CM/ECF system and that a copy of the brief was served by email on

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Upon acceptance of the Court, two copies will be mailed by first class mail to lead counsel as noted above.

Upon acceptance by the Court of the efiled brief, six copies will be filed with Court, via overnight service within the time prescribed by the Court.

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ADDENDUM

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590 06/29/2012

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EXAMINER	
CLARK, JEANNE MARIE	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

BECTON, DICKINSON AND COMPANY
Requester & Respondent

v.

MICHAEL J. VAILLANCOURT
Patent Owner & Appellant

Appeal 2012-003151
Application 95/000,565
Patent 6,699,221 B2
Technology Center 3900

Before RICHARD M. LEBOVITZ, JEFFREY B. ROBERTSON, and RAE LYNN P. GUEST, *Administrative Patent Judges*.

GUEST, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal by the Patent Owner from the Patent Examiner's rejections of claims 1-37 in an *inter partes* reexamination of U.S. Patent 6,699,221 B2, issued March 2, 2004. The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6, 134, and 315. We AFFIRM.

STATEMENT OF THE CASE

The patent in dispute in this appeal is U.S. Patent 6,699,221 B2 (hereinafter, "the '221 patent") owned by inventor Michael J. Vaillancourt (hereinafter "Patent Owner") who is the appellant and real party in interest in this appeal.[1]

A third party request for *inter partes* reexamination under 35 U.S.C. §§ 311-318 and 37 C.F.R. §§ 1.902-1.997 of the '221 patent was filed August 12, 2010, naming Becton, Dickinson and Company as the real party in interest for the third party requester (hereinafter "Respondent").[2] Respondent also filed a Brief in response to Patent Owner's Appeal Brief on September 29, 2011.

The '221 patent generally relates to a "bloodless" over-the-needle catheter. Figure 1 of the '221 patent is reproduced below.

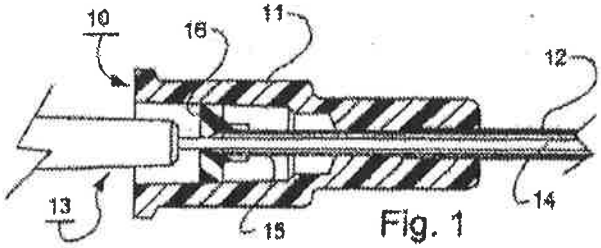

Fig. 1

Figure 1 depicts a cross-sectional view of an over-the-needle catheter including a hub 11 and a cannula 12 extending from and fixed in a distal end of hub 11. An introducer needle 14 extends coaxially through cannula 12 and extends from and is fixed in a distal end of needle hub 13. Appellants describe the

[1] *See* Patent Owner's Appeal Brief, filed August 29, 2011 (hereinafter "App. Br."), at 2.

[2] *See* Request for *Inter Partes* Examination, filed August 12, 2010 (hereinafter "Request"), at 2.

construction of hub 11, cannula 12, introducer needle 14, and needle hub 13 as "conventional." (The '221 patent, col. 2, ll. 31-33 and col. 3, ll. 3-12.)

The catheter of the '221 patent also includes a seal 16 and tube 15 arrangement, as depicted in Figure 1 above ('221 patent, col. 1, ll. 46-49, col. 2, ll. 34-36, col. 3, ll. 13-18).

REJECTIONS

The Examiner rejected the claims as follows:[3]

1. Claims 1-3, 6, 23, and 25 under 35 U.S.C § 102(b) as anticipated by Cox[4] (see Rejections 1 and 31).
2. Claims 1-3, 6, 22, 23, and 25 under 35 U.S.C. § 103(a) as obvious over Cox (see Rejections 2 and 30).
3. Claims 1-3, 6, 16, 24 and 26 under 35 U.S.C. § 103(a) as obvious over Cox in view of Sylvanowicz[5] (see Rejections 3 and 32).
4. Claim 17 under 35 U.S.C. § 103(a) as obvious over Cox in view of Fischell.[6]
5. Claims 1, 3, 6, 10-14, and 18 under 35 U.S.C § 102(b) as anticipated by Luther.[7]

[3] *See* Action Closing Prosecution, dated January 24, 2011, (hereinafter "ACP") at 2-25 and Right of Appeal Notice, dated April 5, 2011, (hereinafter "RAN") at 3 and 6-29.

[4] Cox et al., US 4,935,010, issued June 19, 1990 (hereinafter "Cox").

[5] Sylvanowicz, et al., US 5,304,156, issued April 19, 1994 (hereinafter "Sylvanowicz").

[6] Fischell et al., US 5,295,969, issued March 22, 1994 (hereinafter "Fischell").

6. Claims 1, 3, 6, 10-14, and 18 under 35 U.S.C. § 103(a) as obvious over Luther.
7. Claims 1, 3, 6, 10-14, and 18 under 35 U.S.C. § 103(a) as obvious over Luther in view of Cox.
8. Claims 1, 3, 6, 10-14, 16, and 18 under 35 U.S.C. § 103(a) as obvious over Luther in view of Sylvanowicz.
9. Claim 17 under 35 U.S.C. § 103(a) as obvious over Luther in view of Fischell.
12. Claims 1-3, 6, 13-16 under 35 U.S.C. § 103(a) as obvious over Van Heugten[8] in view of Sylvanowicz.
13. Claim 17 under 35 U.S.C. § 103(a) as obvious over Van Heugten in view of Sylvanowicz and Fischell.
14. Claims 1-3, 6, 10-15, and 20 under 35 U.S.C. § 103(a) as obvious over Van Heugten in view of Luther (see Rejection 14).
15. Claims 1-4, 6, 7, 9, 15, 19, 27, 29, and 30 under 35 U.S.C § 102(b) as anticipated by Vaillancourt '766[9] (*see* Rejections 15 and 33).

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[7] Luther, US 4,842,591, issued June 27, 1989 (hereinafter "Luther").

[8] Van Heugten, US 5,053,014, issued October 1, 1991 (hereinafter "Van Heugten").

[9] Vailancourt, US 4,512,766, issued April 23, 1985. It is believed that the '766 patent misspelled the inventor's name and that the inventor is, in fact, the same Vincent L. Vaillancourt of Livingston, NJ, named in the '221 patent and other references cited herein. Thus, hereinafter the '766 patent will be referred to as "Vaillancourt '766".

16. Claims 1-4, 6-9, 15, 19, and 27-30 under 35 U.S.C. § 103(a) as obvious over Vaillancourt '766 (*see* Rejections 16 and 34).

17. Claims 1-9, 15, and 19 under 35 U.S.C. § 103(a) as obvious over Vaillancourt '766 in view of Vaillancourt '891.[10]

20. Claim 22 under 35 U.S.C. § 103(a) as obvious over Cox in view of Vaillancourt '728.

21. Claim 21 under 35 U.S.C. § 103(a) as obvious over the other rejections of claim 1 further in view of Vaillancourt '728[11] (see Rejections 21-28).

33. Claim 27, 29, and 30 under 35 U.S.C § 102(b) as anticipated by or, alternatively, under 35 U.S.C. § 103(a) as obvious over Vaillancourt '766 (see Rejections 33 and 34).

26. Claim 33 under 35 U.S.C. § 103(a) as obvious over Van Heugten in view of Luther and Vaillancourt '728.

27. Claim 28 under 35 U.S.C. § 103(a) as obvious over Vaillancourt '766, either alone or further in view of Vaillancourt '728 or Vaillancourt '891 and Vaillancourt '728 (see Rejections 27, 28, and 34).

36. Claim 31 under 35 U.S.C. § 103(a) as obvious over Vaillancourt '766 in view of Cox.

38. Claim 32 under 35 U.S.C. § 103(a) as obvious over Vaillancourt '766 in view of Cox and Sylvanowicz.

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[10] Vaillancourt, US 5,669,891, issued September 23, 1997 (hereinafter "Vaillancourt '891").

[11] Vaillancourt, US 5,487,728, issued January 30, 1996 (hereinafter "Vaillancourt '728").

40. Claims 34 and 36 under 35 U.S.C. § 103(a) as obvious over Van Heugten in view of Luther and Cox.

41. Claim 35 under 35 U.S.C. § 103(a) as obvious over Van Heugten in view of Luther and Sylvanowicz.

42. Claim 37 under 35 U.S.C. § 103(a) as obvious over Van Heugten in view of Luther, Cox, and Sylvanowicz (see Rejection 42).

Claims 1, 19 and 20 are independent claims. Patent Owner presents arguments with respect to each rejection separately. We have considered each of Patent Owner's arguments separately. We discuss in detail below Rejections 1-6, 14, 16, 17, 26, 30-32, 34, 36, 38, and 40-42, as enumerated by the Examiner. Based on our decisions regarding these rejections, we find it unnecessary to address the merits of the remaining Examiner's rejections, namely Rejections 7-13, 15, 20-25, 27, 28 and 33, as enumerated by the Examiner. Moreover, we consolidate similar issues in our analysis below, where appropriate.

REPRESENTATIVE CLAIM

Claim 1 is representative and reads as follows (App. Br., Claim App'x 1):

> 1. A bloodless catheter comprising
> a first hub having a bore at a proximal end;
> a cannula fixed in and extending from an opposite distal end of said hub for invasive positioning in a blood vessel; and
> a septum seal mounted in said bore of said hub in circumferentially sealed relation to prevent a flow of fluid from said cannula to said proximal end of said hub, said seal having a weakened central section.

CLAIM INTERPRETATION

The meaning of the limitation "mounted in said bore of said hub in circumferentially sealed relation" is in dispute in this appeal. During reexamination, "claims . . . are to be given their broadest reasonable interpretation

consistent with the specification, and . . . claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (*quoting In re Bond*, 910 F.2d 831, 833 (Fed. Cir. 1990)).

We begin by interpreting the term "mounted" as it appears in the phrase "a septum seal mounted in said bore of said hub." Patent Owner directs us to features described as "mounted" in the '221 patent that are designed to be movable (App. Br. 10-11). However, the term "mounted" is used in the '221 patent alone and with the qualifiers "slidably" and "telescopically" (*see e.g.*, '221 patent, col. 2, ll. 1-3, col. 2, ll. 19-22, and col. 3, ll. 12-15). Therefore, the term "mounted" is not expressly defined in the '221 patent. "Absent an express definition in their specification, the fact that appellants can point to definitions or usages that conform to their interpretation does not make the PTO's definition unreasonable when the PTO can point to other sources that support its interpretation." *In re Morris*, 127 F.3d 1048, 1056 (Fed. Cir. 1997); *see also In re Bigio*, 381 F.3d 1320, 1324-25 (Fed. Cir. 2004) (Absent claim language carrying a narrow meaning, we only limit the claim based on the specification when those sources expressly disclaim the broader definition.); *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (An inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention "with reasonable clarity, deliberateness, and precision.").

The ordinary meaning of the word "mounted" is placed or fixed on or in an appropriate support, or, more generally, "supported."[12] Thus, in addition to embodiments where the septum seal is movable, as described in certain preferred embodiments in the '221 patent, the term "mounted," recited in the claim also clearly encompasses septum seals that are supported in any manner, including a permanent or fixed manner.

The claim also has "a first hub having a bore at a proximal end." Patent Owner contends that the "bore" of the "hub" is precluded from having a recess, which is absent in the figures of the '221 patent (App. Br. 10-11). However, the term "bore" is not defined in the '221 patent, and we decline to limit the meaning to the particular examples in the '221 patent. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments."). The term "bore" generally means a hollow chamber or barrel or the inner surface thereof that is "usually" cylindrical.[13] Thus, a "bore" need not necessarily be cylindrical and recesses formed within a

[12] *See e.g.*, http://www.thefreedictionary.com/mount, sense 6a and 6b, accessed May 31, 2012 (sense 6a "to fix securely to a support" and sense 6b "to place or fix on or in the appropriate support or setting for display or study"); http://www.merriam-webster.com/dictionary/mount, sense 6a, accessed May 31, 2012 ("to attach to a support").

[13] *See e.g.*, http://www.thefreedictionary.com/bore, sense 2 and 3, accessed May 31, 2012 ("a hollow, usually cylindrical chamber or barrel, as of a firearm" and "the interior diameter of a hole, tube, or cylinder"); http://www.merriam-webster.com/medical/bore, sense 1 and 2, accessed May 31, 2012 ("the long usually cylindrical hollow part of something (as a tube or artery)" and "the internal diameter of a tube (as a hypodermic needle, catheter or sound)").

hollow chamber or barrel are not precluded from constituting a portion of the "bore."

The phrase "circumferentially sealed relation," defining the relationship between the seal and bore, is also not defined in the '221 patent. On its face, the phrase means that the septum seal and the bore are related such that a seal is formed around a circumference of the seal. The '221 patent describes an "interference fit" as an example of a "circumferentially sealed relation" ('221 patent, col. 3, ll. 41-46), but the '221 patent does not expressly limit the type of seal to an interference fit. The broad claim language does not limit the type of seal or how the seal is formed, and we decline to read any limitations into the claim from the specification when there is no express teaching to do so. *See Phillips*, 415 F.3d at 1323.

1. ANTICIPATION BASED ON COX (Rejections 1 and 31)

The Examiner rejects claims 1-3, 6, 23, and 25 as anticipated by Cox. Patent Owner presents arguments with respect to claims 1-3 and 6 as a group and presents no separate argument with respect to claim 25 over that of claim 1 (App. Br. 6-9 and 44). Patent Owner presents separate arguments with respect to claim 23 (App. Br. 43-44). Accordingly, we select claims 1 and 23 as representative claims.

Claims 1-3, 6, and 25

The Examiner rejects claim 1 as anticipated by Cox. Figure 7 of Cox is reproduced below.

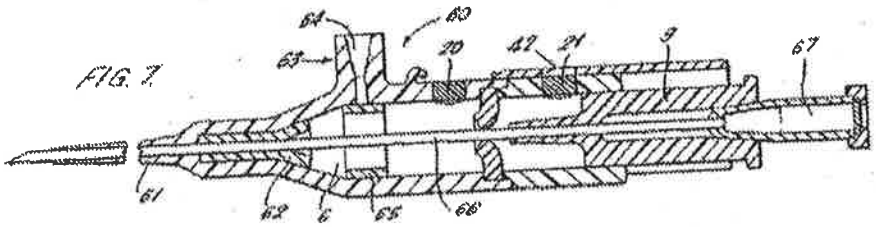

Figure 7 of Cox depicts a sectional elevation view of a device for use in intravenous infusion via a cannula 61 that is integrally formed with a housing 2 (not labeled in Figure 7) (Cox, col. 2, ll. 50-51 and col. 5, ll. 34-45).

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Patent Owner contests the Examiner's finding that certain limitations recited in claim 1 are disclosed in Cox (App. Br. 6-9 and 44). The issue before us is: Under a proper interpretation of the language of claim 1, does the evidence support the Examiner finding that Cox discloses "a cannula fixed in and extending from an opposite distal end of said hub" and "a septum seal mounted in said bore of said hub"? We answer this question in the affirmative.

The Examiner finds that cannula 61 of Cox's catheter is "fixed in and extending from" a "hub" (i.e., housing 2) (ACP 2). In addition, Cox's catheter has "a cannula formed integrally with the housing 2 and communicating with the first chamber 6" (Cox, col. 5, ll. 37-39 and Fig. 7).

Initially, we are not persuaded by Patent Owner's arguments that the claimed cannula does not read on the "trocar 66" and "connection means 8" disclosed in Cox, as the Examiner clearly does not rely on these elements for the claimed "cannula." (App. Br. 7-8; ACP 2).

Patent Owner further argues that the Specification of the '221 patent requires that the hub and cannula be "two separate parts," citing portions of the Specification referring to the cannula as "fixed in and extending from" the hub and stating generally that the Figures show "the cannula 12 being made separate from and of a different material from hub 11" (App. Br. 8) (citing col. 1, ll. 50-53 and col. 3, ll. 3-9).

To the extent that Patent Owner is arguing that the claimed invention does not read on Cox's catheter because cannula 61 is not a separate part from housing 2 (which is not labeled in Figure 7 above), we see no reason to conclude that the phrase "fixed in and extending from" would necessarily require that the cannula and the hub be "separate" as suggested by the Patent Owner. The term "fixed" commonly means "securely placed or fastened."[14] We are not persuaded that the Specification expressly requires that the term "fixed" precludes an integral structure merely because the Figures of the '221 patent illustrate a separable structure. We decline to strictly limit the scope of the claims to the embodiments in the figures of the '221 patent. *See Phillips*, 415 F.3d at 1323.

The Examiner finds that membrane 4 is a septum seal "mounted in said bore of said hub in circumferentially sealed relation" (ACP 2-3). Patent Owner contends that membrane 4 is not "mounted in said bore of said hub" because it is "held in a shoulder recess of one housing part by a second housing part" and "is not capable of being moved as the membrane is fixed in place" (App. Br. 9). Based on the claim interpretation discussed above, the phrase "mounted in said bore of said hub" does not preclude the septum seal from being permanently fixed

[14] http://www.merriam-webster.com/dictionary/fixed, sense 1a, accessed June 14, 2012.

or disposed in a recess that defines a portion of a bore. To the extent that Patent Owner is arguing that a bore cannot be defined by more than one housing part, Patent Owners have provided no persuasive evidence that the term "bore" should be so limited.

Accordingly, considering the broadest reasonable interpretation of the terms recited in claim 1, we agree with the Examiner's finding that that claim 1 reads on the device structure described in Cox.

Claim 23

Claim 23 depends from claim 1 and further requires that the "seal is sealed in an interference fit manner to said bore of said hub, said interference fit determining the maximum pressure allowable in said catheter before leakage into said proximal end of said hub occurs" (App. Br., Claim App'x 4-5).

Cox teaches that membrane 4 is retained under "radial compression" which is "achieved by making the membrane a force fit with the recess 5" (Cox, col. 5, ll. 23-24). Patent Owner contends that Cox does not disclose any relation between the radial compression and the maximum pressure allowable in the catheter before leakage into the proximal end of the hub occurs (App. Br. 44). The Examiner finds that a force fit is an "interference fit that would determine the maximum pressure allowable prior to leakage" (ACP 21-22).

We agree with Patent Owner that Cox does not expressly disclose a relationship between the "force fit" of the membrane and the maximum pressure allowable before leakage. However, "a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency." *In re Omeprazole Patent Litigation*, 483 F.3d 1364, 1373 (Fed. Cir. 2007). "Under the

principles of inherency, if a structure in the prior art necessarily functions in accordance with the limitations of a process or method claim of an application, the claim is anticipated." *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986).

Thus, the issue before us is: does the evidence support the Examiner's view that an interference fit would necessarily function to determine the maximum pressure allowable prior to leakage? We answer this question in the affirmative.

Cox teaches that blood spillage is prevented by the self-sealing action of membrane 4, which "by virtue of its elastomeric properties is assisted by radial compression within the annular recess 5 so that the valve means returns to its closed condition in which the first and second chamber 6 and 7 respectively are isolated from one another" (Cox, col. 6, ll. 3-5 and col. 5, ll. 7-12). In other words, Cox teaches that the radial compression of the membrane 4 is what prevents blood leaking from the distal first chamber 6 to the second proximal chamber 7. We agree with the Examiner that the interference fit taught by Cox necessarily dictates the maximum pressure at which blood would leak around the membrane 4. Patent Owner has not directed us to sufficient rationale or evidence to undermine this reasoning.

2. OBVIOUSNESS BASED ON COX (Rejections 2 and 30)

Claims 1-3, 6, 22, 23, and 25

The Examiner further rejects claims 1-3 and 6 as obvious over the teachings of Cox (ACP 3). We need not go into the merits of Patent Owner's arguments with respect to the rejection based on our affirmance of the Examiner's anticipation rejection above. After all, it is well established that lack of novelty is the ultimate or epitome of obviousness. *In re Fracalossi*, 681 F.2d 792, 794 (CCPA 1982) ("Though the composition might have been obvious, though not anticipated, it

cannot have been anticipated and not have been obvious. Thus evidence establishing lack of all novelty in the claimed invention necessarily evidences obviousness.").

Patent Owner does not present any arguments with respect to claims 22, 23, and 25 (Rejection 30), which depend from claim 1 (*see generally* App. Br. 43). Accordingly, we affirm the Examiner's rejection of claims 1-3, 6, 22, 23, and 25 under 35 U.S.C. § 103.

3. OBVIOUSNESS BASED ON COX AND SYLVANOWICZ

(Rejections 3 and 32)

Claims 1-3 and 6, 16, 24, and 26

Patent Owner presents arguments with respect to claims 1-3 and 6 as a group and presents no separate argument with respect to claims 16, 24, and 26 over that of claim 1 (App. Br. 14 and 44). Accordingly, we select claim 1 as a representative claim.

Figure 2 of Sylvanowicz is reproduced below.

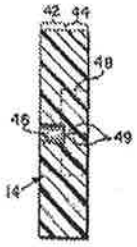

Fig. 2

Figure 2 depicts an enlarged sectional view of a one-piece self-sealing valve element 14 of the invention of Sylvanowicz in which an outer half thickness 42 is formed with a central aperture 46 which extends only to a depth of about the half thickness of the gasket 14 (Sylvanowicz, col. 2, ll. 43-45 and col. 3, ll. 36-39). The

Examiner concludes that it would have been obvious for one of ordinary skill in the art to have combined the central aperture of the seal of Sylvanowicz with the device and membrane of Cox to meet the limitation of a seal with a weakened central section (ACP 4).

Patent Owner contends that one of ordinary skill in the art would not have combined the teachings of Cox and Sylvanowicz because the membrane of Cox does not require a seal against objects directed therethrough, but the seal of Sylvanowicz teaches a valve capable of sealing against a guidewire or catheter directed therethrough (App. Br. 13; *see* Sylvanowicz, col. 4, ll. 7-30). A reference "teaches away" when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the Appellants' invention. *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). We do not agree that the teaching in Cox directs one of ordinary skill in the art against adding a central aperture that would seal against objects directed therethrough. To the contrary, Sylvanowicz discloses that the valve is capable of sealing against an object directed therethrough, which is an advantage that would have directed the skilled artisan to make the modification proposed by the Examiner. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 550 U.S. at 417.

Patent Owner also contends that the aperture of Sylvanowicz would "pucker" and not come together in a sealed manner due to the radial compression on the membrane 4 taught by Cox (App. Br. 13-14). Although a combination of references would be non-obvious when the combination would produce an

inoperative device, *see McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001), Patent Owner has provided no more than mere speculation, without evidence, that the radial compression of Cox would not function with the central aperture of Sylvanowicz. Appellants' attorney arguments do not take the place of evidence in the record. *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974).

4. OBVIOUSNESS BASED ON COX AND FISCHELL (Rejection 4)

Claim 17

Claim 17 depends from claim 1 and further recites "a stylet extending through said weakened section of said seal and said cannula" (App. Br., Claim App'x 3). The Examiner finds that Fischell evinces that using a stylet with catheters was well known in the art (ACP 5). According to the Examiner, it would have been obvious to use a stylet with the catheter of Cox because to do so would have been no more than the predictable use of a known element according to its established function (*id.*)

Patent Owner alleges that "the devices of Cox and Fischell are distinctly different devices" in that Cox discloses a device for sampling or infusion of liquids and Fischell discloses a vascular access device (App. Br. 14). Although Patent Owner identifies that the catheter devices of Cox and Fischell are different, Patent Owner does not address the Examiner's specific reasoning articulated in the rejection or explain why the Examiner's position is deficient.

To the extent that the Patent Owner is arguing that Cox and Fischell are non-analogous art, we disagree. "Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor, regardless of the problems addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the

particular problem with which the inventor is involved." *In re Clay*, 966 F.2d 656, 658-59 (Fed. Cir. 1992).

Cox and Fischell both teach catheter devices for intravenous access. Fischell teaches that its "stylet" is a needle used to penetrate the skin and the femoral artery so as to allow the device 10 to enter the artery (Fischell, col. 2, l. 60 to col. 3, l. 5). Similarly, Cox teaches "a needle or catheter may be passed through the duct 11, the membrane 4 and hence through the cannula into the patient" (Cox, col. 5, ll. 28-33). Thus, Cox and Fischell appear to be from the same field of endeavor in that they are both directed to passing objects into and out of the vessels of a patient via a cannula or catheter.

5. ANTICIPATION AND OBVIOUSNESS BASED ON LUTHER

(Rejections 5 and 6)

The Examiner rejects claims 1, 3, 6, 10-14, and 18 as anticipated by, and as obvious over, the teachings of Luther. For both rejections, Patent Owner presents arguments with respect to claim 1 and presents no separate argument with respect to claims 2, 3, 6, 13 and 14 over that of claim 1 (App. Br. 15-20). Patent Owner presents separate arguments with respect to claim 10 and presents no separate arguments with respect to claims 11 and 12 over that of claim 10 (App. Br. 17-18 and 20). Accordingly, we select claims 1 and 10 as representative claims.

Claims 1, 3, 6, 13, 14, 18

Figure 3 of Luther is reproduced below.

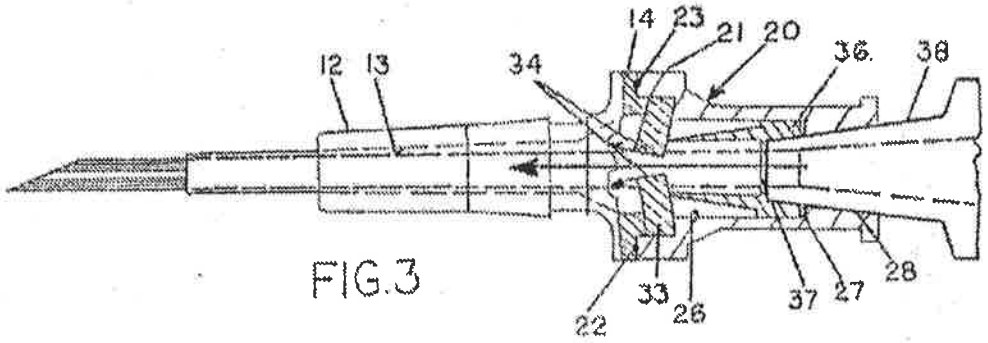

FIG.3

Figure 3 of Luther is a sectional side elevation view of a connector device having a septum seal 33 for providing a sterile closure for use with I.V. and syringe systems, with the septum portion being open for liquid flow (Luther, col. 1, ll. 14-18 and 52-54).

Patent Owner contests the Examiner's finding that certain limitations recited in claim 1 are disclosed in Luther, namely a septum seal mounted in a bore, a seal with a weakened central section, and a septum seal in a circumferentially sealed relation (App. Br. 15-17).

The issue before us is: Under a proper interpretation of the language of claim 1, does the evidence support the Examiner finding that Luther describes "a septum seal mounted in said bore of said hub in a circumferentially sealed relation" having a "weakened central section"? We answer this question in the affirmative.

The Examiner finds that septum 33 is "mounted in said bore of said hub in circumferentially sealed relation" (ACP 5). Patent Owner contends that 33 is not "mounted in said bore of said hub" because it is fitted into "a space 32 between the faces of the proximal fitting 11 and the distal fitting 20" and "is not capable of being moved as the septum 33 is fixed in place" (App. Br. 15-16). Based on the

claim interpretation discussed above, the phrase "mounted in said bore of said hub" does not preclude the septum seal from being permanently fixed or disposed in a recess that defines a portion of a bore. Therefore, Patent Owner's argument is not persuasive.

Regarding the septum seal being in circumferentially sealed relation to the bore and having a weakened central section, Patent Owner merely asserts that these claim features are not taught by Luther (App. Br. 16). A general allegation that the art does not teach the claim limitations is no more than merely pointing out the claim limitations. 37 C.F.R. § 41.67(c)(1)(vii) ("A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim."). In any event, such statements do not address the Examiner's specific findings and support therefore (*see* ACP 5, citing Luther, col. 1, ll. 58-61, col. 2, ll. 19-49, and Figures 1-3) articulated in the rejections or explain why these findings are not supported by the evidence.

Patent Owner also contends that a hub cannot be defined by more than one fitting part (i.e. proximal end fitting 11 (not shown in Fig. 3 reproduced above) and distal fitting 20 of Luther), citing portions of the Specification referring to "hub 11" and stating generally that "Figures 1 and 3 illustrate hub 11 as a one piece member" (App. Br. 16-17) (citing '221 patent, col. 1, ll. 50-53, col. 3, ll. 3-9, and col. 4, ll. 1-5). We discern no reason to conclude that the term "hub" would necessarily require a structure formed from only one part or fitting, as suggested by the Patent Owner. The term "hub" commonly is a base by which a needle is

attached to a device.[15] We are not persuaded that the Specification expressly requires that the term "hub" precludes the two piece structure taught by Luther. We decline to strictly limit the scope of the claims to the embodiments in the figures of the '221 patent. *See Phillips*, 415 F.3d at 1323. Patent Owner has provided no persuasive evidence that the term "hub" should be so limited.

Accordingly, considering the broadest reasonable interpretation of the terms recited in claim 1, we agree with the Examiner's findings that that claim 1 of the '221 patent reads on the device structure described in Luther. Thus, we affirm the rejection of claims 1, 3, 6, 13, 14, and 18 as both anticipated by and as obvious in view of Luther. *See Fracalossi*, 681 F.2d at 794.

Claims 10-12

Claim 10 depends from claim 1 via claim 6 and further recites "a piercing ring mounted on said seal for pushing through said weakened section of said seal in a direction towards said cannula to define a flow path through said seal" (App. Br., Claim App'x 2). The Examiner finds that Luther teaches a piercing ring 35b mounted on the seal that functions as recited in claim 10 because Luther teaches that "a typical plug spacing is about 0-10 mils from the septum" (ACP 7; Luther, col. 2, ll. 30-34). Patent Owner contends that Luther does not teach that the piercing ring 35b is mounted on the seal but rather that the plug is "spaced" from the seal, and, even if spaced 0 mils from the seal, the plug would be contacting but not "mounted on" the septum 33 (App. Br. 17-18).

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[15] http://www.merriam-webster.com/medical/hub, accessed June 19, 2012 ("the enlarged base by which a hollow needle may be attached to a device (as a syringe)").

Based on the interpretation of the term "mounted" discussed above as generally meaning "supported," we agree with the Patent Owner that a teaching of the plug merely contacting the septum seal is not a teaching that the plug is supported by the seal.

However, the Examiner alternatively concludes that it would have been obvious to mount the plug 35b on the septum seal 33 so that the plug will remain in contact with the septum (ACP 7). Patent Owner contends that there would be no rationale to mount the plug on the septum seal because Luther teaches that the plug is spaced from the seal (App. Br. 20).

The Examiner has provided a sufficient reasoning as to why the skilled artisan would use the seal to support the plug taught by Luther, namely, to provide that the plug remains in contact with the seal (ACP 7). Patent Owner has not addressed the Examiner's reasoning nor directed us to any rationale or evidence by which we would determine the Examiner's reasoning to be unsound.

Patent Owner's further arguments directed to the obviousness rejection of claim 10 based on Luther discuss "membrane opener 120" and "membrane 110," which appears to be arguments directed to prior art other than Luther.

Accordingly, we reverse the Examiner's rejection of claims 10-12 based on anticipation by Luther, but we affirm the Examiner's rejection of claims 10-12 based on obviousness in view of Luther.

6. OBVIOUSNESS BASED ON VAN HEUGTEN AND LUTHER

(Rejection 14)

The Examiner rejects claims 1-3, 6, 10-15, and 20 as obvious over Van Heugten and Luther. Patent Owner presents with arguments respect to claim 1 and

presents no separate argument with respect to claims 2, 3, 6, 13 and 14 over that of claim 1 (App. Br. 27-29). Patent Owner presents separate arguments with respect to claims 10, 15 and 20 and presents no separate arguments with respect to claims 11 and 12 over that of claim 10 (App. Br. 28-30). Accordingly, we select claims 1, 10, 15 and 20 as representative claims.

Claims 1-3 and 6, 13 and 14

Figure 3 of Van Heugten is reproduced below.

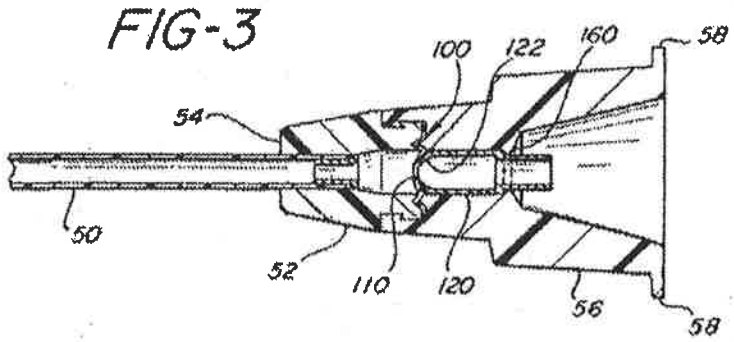

Figure 3 of Van Heugten depicts a detailed cross sectional view of a catheter assembly having a catheter 50 and catheter hub 52 incorporated with a membrane assembly 100 comprising a one-directional valve membrane 110 (Van Heugten, col. 2, ll. 6-12 and col. 3, l. 59-col. 4, l. 5).

Patent Owner contests the Examiner's finding that certain limitations recited in claim 1 are disclosed in Van Heugten, namely a septum seal mounted in a bore in a circumferentially sealed relation, and contends that one of ordinary skill in the art would not have modified the membrane 110 of Van Heugten with the weakened section (slits 34) of Luther (App. Br. 27-28).

The issues before us are: Under a proper interpretation of the language of claim 1, does the evidence support the Examiner finding that Van Heugten

describes "a septum seal mounted in said bore of said hub in a circumferentially sealed relation" and does the evidence support the Examiner's conclusion that one of ordinary skill in the art would have modified the membrane 110 of Van Heugten with the weakened central section of Luther? We answer both of these questions in the affirmative.

The Examiner finds that membrane 110 is "mounted in said bore of said hub in circumferentially sealed relation" (ACP 12). Patent Owner contends that membrane 110 is not "mounted in said bore of said hub" because it is "has an outer periphery sandwiched between the catheter hub 52 and a proximal portion 56" (App. Br. 24 and 27). Based on the claim interpretation discussed above, the phrase "mounted in said bore of said hub" does not preclude the septum seal from being permanently fixed, disposed in a recess that defines a portion of a bore, or sandwiched between two pieces that define a hub. Accordingly, we are not persuaded by Patent Owner's argument.

Regarding the septum seal being in circumferentially sealed relation to the bore, Patent Owner merely asserts that these claim features are not taught by Van Heugten (*id.*). A general allegation that the art does not teach the claim limitations is no more than merely pointing out the claim limitations. *See* 37 C.F.R. § 41.67(c)(1)(vii). In any event, such statements do not address the Examiner's specific findings and support therefore (*see* ACP 12, citing Van Heugten, col. 1, ll. 4-27, col. 2, ll. 45-50, col. 3, l. 59-col. 4, l. 49, and Figures 2, 3, and 4a-4c) articulated in the rejections or explain why the Examiner's findings are not supported by the evidence.

Patent Owner contends that the Y-shaped slit 34 of Luther would compromise the sealability of membrane 110 of Van Heugten. According to

Patent Owner, Luther does not require the Y-shaped slit 34 to be sealable against objects directed therethrough, as Luther does not disclose an object that passes through gasket 33 or to seal against the introducer needle (*see generally* Luther), and Van Heugten discloses that the seal is sealed prior to piercing by an introducer needle (*see* Van Heugten, col. 4, ll. 7-30). (App. Br. 27-28).

We do not agree that Van Heugten directs one of ordinary skill in the art against adding the Y-shaped slits of Luther merely because the central portion of Luther does not require an initial piercing by a needle. Both Luther and Van Heugten teach that the seal must be resealable and one-directional to prevent the flow of blood out of the catheter (*see* Van Heugten, col. 4, ll. 6-29; Luther, col. 1, ll. 32-44). We agree with the Examiner that the use of the Y-shaped slits 34 of Luther would be a predictable use of a known resealable one-way valve according to its established function of preventing backflow of blood from a catheter. *See KSR*, 550 U.S. at 417 (The question to be asked is "whether the improvement is more than the predictable use of prior art elements according to their established functions.").

Further, Patent Owner argues that, because Luther does not teach gasket 33 seals against an element passing therethrough, one skilled in the art would find no teaching in Luther "to place an inverted Y-shaped slit in the membrane 110 of Van Heugten that is to seal against an introducer needle 24" (App. Br. 27-28). Patent Owner's argument presupposes that Van Heugten requires a membrane 110 to seal against introducer 24. However, Patent Owner directs us to no persuasive evidence that Van Heugten requires a seal against the introducer needle 24, and we find no such requirement in the teachings of Van Heugten. Rather, we find that Van Heugten teaches against a tight seal against the needle in that it teaches a

"'duck-bill' valve or valve of similar configuration" as an example of a valve that provides "no frictional drag on needle 24 during its retraction from the catheter 50" (Van Heugten, col. 4, ll. 19-27).

Claim 10-12

In addition to those arguments discussed above with respect to the anticipation and obviousness rejections of claim 10 based on Luther, Patent Owner contends (a) that neither plug 35b of Luther nor membrane opener 120 of Van Heugten "pass through" the respective seals and (b) that if membrane opener 120 were mounted on membrane 110, the opener 120 would not be able to deform member 110 because the membrane 110 needs to slide relative to the membrane opener 110 in order to be opened (App. Br. 28).

Patent Owner equates the phrase "for pushing through" with "pass through," suggesting that claim 10 requires an express teaching that the piercing ring is pushed so as to fully pass through the seal. Patent Owner's interpretation of claim 10 does not comport with the broadest reasonable interpretation of claim 10. Claim 10 recites "a piercing ring mounted on said seal *for pushing through* said weakened section of said seal in a direction towards said cannula *to define a flow path through said seal*" (App. Br., Claim App'x 2) (emphasis added).

We conclude that the express language of claim 10 requires that the piercing ring "push through" the seal only to the extent that it defines a flow path through said seal. Patent Owner has directed us to no evidence or reasoning for us to import a requirement for the piercing ring to fully "pass through" the seal. We agree with the Examiner that piercing ring 35 of Luther functions to push through the seal far enough that such a flow path is defined (*see* Figure 1).

Further, Patent Owner has directed us to no evidence in support of the contention that the plug 35b or opener 120 would not function if "mounted," or supported, by the respective seals of Luther and Van Heugten. Attorney arguments do not take the place of evidence in the record. *Pearson*, 494 F.2d at 1405.

Claim 15

Claim 15 depends from claim 1 and further requires "a needle hub telescopically mounted in said bore of said first hub and an introducer needle fixed in said needle hub and extending through said seal in a sealed relation and through said cannula" (App. Br., Claim App'x 3).

The Examiner finds that Van Heugten teaches a needle hub 20 telescopically mounted in the bore of the first hub with an introducer needle 24 fixed therein (ACP 13). Patent Owner disagrees and contends that Van Heugten does not teach a needle hub mounted in hub 52 nor an introducer needle fixed in a needle hub (App. Br. 29). Once again we turn to the broadest reasonable interpretation of the term "mounted." As discussed above, we interpreted "mounted" as generally meaning "supported." There is no requirement that the needle hub be *directly* supported by the hub. As such, Van Heugten teaches that the needle hub 20 (i.e., the portion which holds the needle 24 in place) is indirectly supported by hub 52 via the telescopic contact of needle guard tip 60 and hub 52 (*see e.g.*, Van Heugten, col. 2, ll. 50-55 and Figure 2). Patent Owner has failed to explain why the Examiner's finding would not meet the requirements of claim 15.

Alternatively, the Examiner concludes that it would have been obvious to the skilled artisan to design needle hub 20 and needle guard tip 60 in one unit or so that the needle guard tip 60 and needle hub 20 are mounted in the hub 52 (ACP

14). Patent Owner argues that making the structure unitary would be contrary to the teachings of Van Heugten, which discloses a separate needle guard tip 60. However, Patent Owner directs us to no teaching in Van Heugten that would deter the skilled artisan from combining the tip guard 60 and needle hub 20 into a single structure, as Patent Owner has directed us to no persuasive evidence to indicate that these two components are required to be separate. The reasons for the skilled artisan to combine separate structures into a single structure may include, for example, the reduced cost of forming a one piece structure rather than two. *See In re Thompson,* 545 F.2d 1290, 1294 (CCPA 1976) (motivation may be found in economic factors alone).

Claim 20

Independent claim 20 requires a male luer adaptor "being sized to engage and push said piercing ring through said slit in said seal to communicate said adaptor with said cannula" (App. Br., Claim App'x 4). Based on this language, Patent Owner presents substantially the same arguments discussed above with respect to claim 10 (App. Br. 29-30).

We do not find Patent Owner's arguments persuasive for the reasons discussed above. Moreover, we note that the quoted language of claim 20 is directed only to the size of the male luer adaptor, not to any structural requirements of the piercing ring or the seal. Accordingly, we agree with the Examiner that both Van Heugten and Luther teach male luer adaptor of a size capable of performing the claimed function. Patent Owner presents no arguments regarding the described size of the male luer adaptors of Van Heugten and Luther.

7. OBVIOUSNESS BASED ON VAN HEUGTEN, LUTHER, AND VAILLANCOURT '728 (Rejection 26)

The Examiner rejects claims 21 and 33 as obvious over Van Heugten, Luther, and Vaillancourt '728. Patent Owner presents arguments with respect to claim 21, but presents no separate argument with respect to claim 33 over that of claim 20 (App. Br. 42). Accordingly, we address claim 21, but affirm the rejection of claim 33 for the reasons discussed above with respect to claim 20.

Claim 21

Claim 21 depends from claim 1 and further requires that the "seal is compressed approximately 6% to provide a leakage pressure exceeding 10 psi" (App. Br., Claim App'x 4).

Vaillancourt '728 teaches that a seal with "an initial compression of 5% to 10% of its outer diameter and made of a thickness of 0.050 inches may be pierced over twenty five times with no leakage once subjected to 30 psig air pressure" (Vaillancourt '728, col. 2, ll. 60-64). Further, Van Heugten teaches that blood flowing out of the body has an approximate pressure of 2 psi and that "membrane 110 is configured so that it withstands outwardly directional flow of blood greater than about 3 psi or well above the normal human limit" (Van Heugten, col. 4, ll. 14-18). The Examiner concludes that it would have been obvious to one of ordinary skill in the art that a radial compression of the seal should be at least 6% to predictably result in a desirable leakage pressure over 10 psi (ACP 20).

Patent Owner argues that Van Heugten does not teach that valve membrane 110 is or can be radially compressed or that such a compression results in a desired leakage pressure over 10 psi (App. Br. 41-42). Additionally, Patent Owner

contends that the Examiner presents no evidence to support this position. (App. Br. 41.)

We are not persuaded by Patent Owner's arguments. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 550 U.S. at 417. Van Heugten teaches a desire to provide a seal that can withstand pressures "well above the normal human limit" of 2 psi. Vaillancourt '728 teaches that one way to achieve a seal that can withstand pressures up to 30 psi is to provide radial compression of 5-10%. Accordingly, the Examiner's position is supported by the evidence of record. In contrast, Patent Owner has not provided sufficient evidence or reasoning that modifying the seal of Van Heugten by applying a radial compression of up to 10%, as taught by Vaillancourt '728, is beyond the skill of an ordinary artisan.

8. OBVIOUSNESS BASED ON VAN HEUGTEN, LUTHER, AND COX
(Rejections 40 and 42)

The Examiner rejects claims 34 and 36 as obvious over Van Heugten, Luther, and Cox. The Examiner further rejects claim 37 as obvious over Van Heugten, Luther, Cox, and Sylvanowicz.

With respect to claim 34, Patent Owner relies on the same arguments discussed above with respect to the rejection of claim 23 as anticipated by Cox, i.e., that an interference fit would determine the maximum pressure allowable prior to leakage (App. Br. 47).

With respect to claims 36 and 37, Patent Owner presents no arguments over those presented above with respect to claim 20 as obvious over Van Heugten in view of Luther (App. Br. 47-48).

For the reasons discussed above with respect to claims 23 and 20, we affirm the Examiner's rejection of claims 34, 36, and 37.

9. OBVIOUSNESS BASED ON VAN HEUGTEN, LUTHER, AND SYLVANOWICZ (Rejection 41)

Claim 35

Claim 35 depends from claim 20 and further recites that the seal "has an internal recess defining a weakened central section" (App. Br., Claim App'x 4). Patent Owner contends that one of ordinary skill in the art would not have combined the teachings of Van Heugten or Luther and Sylvanowicz because the membrane of Luther and Van Heugten do not require a seal against objects directed therethrough, whereas the seal of Sylvanowicz includes a valve capable of sealing against a guidewire or catheter directed therethrough (App. Br. 22, 25, and 47-48). We do not agree that Luther or Van Heugten directs one of ordinary skill in the art against adding a central aperture that would seal against objects directed therethrough. To the contrary, Sylvanowicz's disclosure that the valve is capable of sealing against an object directed therethrough is an advantage that would have directed the skilled artisan to make the modification proposed by the Examiner. *See KSR*, 550 U.S. at 417.

10. OBVIOUSNESS REJECTIONS BASED ON VAILLANCOURT '766
(Rejections 16, 17, 34, 36, and 38)

The Examiner rejects claims 1-4, 6-9, 15, 19, and 27-30 as obvious over Vaillancourt '766. Patent Owner presents arguments with respect to claim 1 and presents no separate argument with respect to claims 2, 3, 6, 9 and 15 over that of claim 1 (App. Br. 36-37). Patent Owner presents separate arguments with respect to claims 4, 7, 8, 19, 27 and 29 (App. Br. 28-30, 32-33, and 45-46). Patent Owner presents no separate arguments with respect to claims 28 and 30 over that of claim 19 (App. Br. 45-46). Accordingly, we select claims 1, 4, 7, 8, 19, 27 and 29 as representative claims.

The Examiner further rejects claims 1-9, 15, and 19 as obvious over Vaillancourt '766 in view of Vaillancourt '891. Patent Owner makes substantially identical arguments with respect to claims 1, 4, 7, 8, and 19, and presents no arguments with respect to claim 5 over those presented with respect to claim 1. Accordingly, claim 5 stands or falls with claim 1.

The Examiner further rejects claim 31 as obvious over Vaillancourt '766 in view of Cox and claim 32 as obvious over Vaillancourt '766 in view of Cox and Sylvanowicz. For both of these rejections, the Patent Owner presents no arguments over those presented with respect to claim 19. Accordingly, claims 31 and 32 stand or fall with claim 19.

Claims 1, 2, 3, 5, 6, 9 and 15

Figure 3 of Vaillancourt '766 is reproduced below.

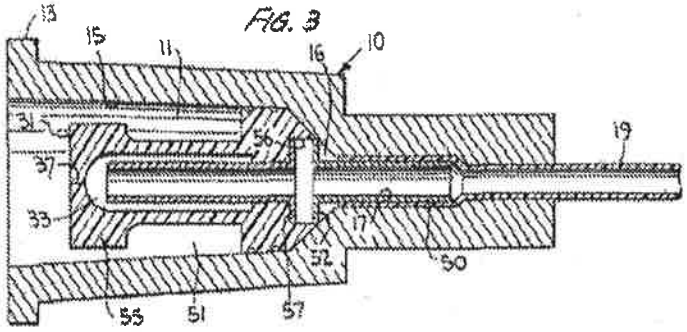

FIG. 3

Figure 3 of Vaillancourt '766 depicts a sectional view of a catheter assembly having a valve member 55 with an outwardly extending annular flange 52 that engages the wall in chamber section 16 in an interference fit (Vaillancourt '766, col. 3, ll. 32-33 and col. 6, ll. 51-68).

Patent Owner contests the Examiner's finding that certain limitations recited in claim 1 are disclosed in Vaillancourt '766, namely that valve member 55 is not a "septum seal" as postulated by the Examiner and that the valve end 31 of valve member 55 is spaced from the hub wall 15 and thus not "in a circumferentially relation" (App. Br. 31).

The issue before us is: Under a proper interpretation of the language of claim 1, does the evidence support the Examiner finding that Vaillancourt '766 describes "a septum seal mounted in said bore of said hub in a circumferentially sealed relation"? We answer this question in the affirmative.

Patent Owner contends that the valve member 55 of Vaillancourt '766 is not a "septum seal" without providing a definition of the term. The term "septum seal" is also not expressly defined in the '221 patent. Patent Owner cites portions of the Specification referring to the septum seal and including references to Figure 2 describing the septum seal 16 as "of generally T-shaped construction having a tubular portion 17 which fits over the tube 15 in a stretch-fit manner" and "a cap

15 integral with the tubular portion" (App. Br. 31-32) (citing col. 1, ll. 54-56, col. 2, ll. 32-36, and col. 3, ll. 12-16, 19-22, and 35-37).

We discern no reason to conclude that the phrase "septum seal" would necessarily require a seal having the particular shape illustrated in the Figures of the '221 patent, as suggested by the Patent Owner. The term "septum" commonly means "a dividing wall separating two spaces."[16] We are not persuaded that the Specification of the '221 patent excludes a seal of the shape described in Vaillancourt '766, which similarly functions as a wall that divides hub 10 into a proximal chamber 11 and a distal chamber. We decline to strictly limit the scope of the claims to the embodiments in the figures of the '221 patent. *See Phillips*, 415 F.3d at 1323.

The Examiner finds that valve member 55 is "mounted in said bore of said hub in circumferentially sealed relation" (ACP 15). While admitting that valve member 55 "has an enlarged support end 56 that contacts a chamber wall 15 in a friction fit" (App. Br. 30-31), Patent Owner contends that valve member 55 is not "mounted in said bore of said hub in a circumferentially sealed relation" because near end 31 is spaced from the hub wall 15 (App. Br. 32). Based on the claim interpretation discussed above, the phrase "mounted in said bore of said hub" does not preclude the septum seal from being supported circumferentially at one end and extended freely into space at another end. Vaillancourt '766 teaches that the "outer periphery [i.e., circumference] of the support end of valve member 55

[16] http://www.merriam-webster.com/medical/septum, accessed June 24, 2012 ("a dividing wall or membrane especially between bodily spaces or masses of soft tissue").

contacts chamber wall in a friction fit [i.e., sealed relation]" (Vaillancourt '766, col. 6, ll. 64-66).

Accordingly, considering the broadest reasonable interpretation of the term "mounted" recited in claim 1, we agree with the Examiner's finding that that claim 1 of the '221 patent reads on the device structure described in Vaillancourt '766.

Claim 4

Claim 4 depends from claim 1 and further requires that the "seal is slidably mounted in said bore" (App. Br., Claim App'x 1). The Examiner finds that valve member 55 is slidably mounted in that Vaillancourt '766 teaches that valve member 55 axially collapses along the relatively thin-walled section 54 existing between the thicker end sections of the valve member, as illustrated in Figure 2 of Vaillancourt '776 reproduced below with respect to valve member 30 (ACP 15; RAN 17-18) (citing Vaillancourt '766, col. 6, l. 68 to col. 7, l. 4).

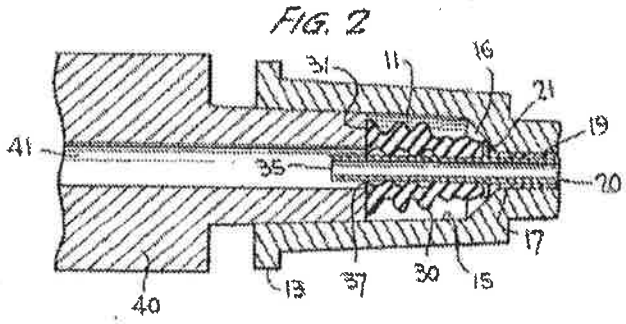

Figure 2 depicts a sectional view of a catheter assembly having a similar valve member 30 shown with a male luer adapter 40 inserted into the catheter hub and axially collapsing the valve member 30 around insert member 20 (Vaillancourt '766, col. 3, ll. 29-31 and col. 5, ll. 47-51). Vaillancourt '766 teaches that valve

member 55 of the embodiment of Figure 3 (above) axially collapses similar to valve member 30 in Figure 2 (Vaillancourt '766, col. 6, l. 68 to col. 7, l. 3).

Patent Owner's arguments focus on the fact that the valve end 31 of valve member 30 in Figure 2 (or 55 in Figure 3) is not mounted in the bore and that support end 56 (Figure 3) is not described as slidably mounted, but rather is fixed in place (App. Br. 33). Patent Owner further states "[l]ikewise, the collapsible thin-walled section 54 of the valve member 55 [or 30 in Figure 2] cannot be read as slidably mounted in the hub 10" (*id.*). Patent Owner's arguments focus on the fact that the various portions of valve member 55, i.e., support end 56, valve end 31, and the thin-walled section 54, individually cannot meet the requirements of claim 4. However, Patent Owner fails to address the fact that the Examiner finds the mounting and axial movement of valve member 55, as a whole, meets the requirements of the claim 4. Accordingly, we are unconvinced that the Examiner's position, which is based on sufficient rational underpinnings, is improper.

Claim 7

Claim 7 depends from claim 1 via claim 6 and further requires "a tube mounted in said weakened section of said seal and extending into said cannula" (App. Br., Claim App'x 2). The Examiner finds that insert member (tube) 20 disclosed in Vaillancourt '766 is mounted in the weakened section 37 of valve end 31 of valve member 30 in Figure 2 and extends into the cannula 19 (ACP 15; RAN 18).

Patent Owner, referencing Figure 1, contends that valve member 30 is axially and radially spaced from insert member 20 and, thus, cannot be mounted thereon (App. Br. 33-34).

The Examiner reasonably finds that the claim 7 reads on the valve member when the luer adaptor 40 is inserted into hub 10, as illustrated in Figure 2, when valve member 55/30 is axially collapsed onto, and thus supported by, tube 20. We see no reason to read the requirements of claim 7 to exist only when no luer adaptor is present, and Patent Owner has provided no evidence or reasoning for us to do so.

Claim 8

Claim 8 depends from claim 1 via claims 6 and 7 and further requires the seal to have "a tubular portion receiving said tube in a stretch fit manner" (App. Br., Claim App'x 2). As shown in Figure 2, weakened section 37 of the valve end 31 of valve member 30, is tubular and provided in a stretch fit manner over inner tube 20 (*see* Figure 2).

As with claim 7 above, Patent Owner's arguments are based on Figures 1 and 3 in which the luer adaptor 40 has not yet been applied (App. Br. 36).

Again, the Examiner reasonably finds that the claim 8 reads on the valve member when the luer adaptor 40 is inserted into hub 10, as illustrated in Figure 2, when a tubular portion of valve member 55 receives tube 20 in a stretch fit manner. We discern no reason to read the requirements of claim 8 to exist only when no luer adaptor is present, and Patent Owner has provided no evidence or reasoning for us to do so.

Claim 19, 28 and 30-32

With respect to independent claim 19, Patent Owner provides an additional argument that Vaillancourt '766 does not teach a "bloodless" catheter because

blood would be allowed to pass into the space between insert member tube 20 and the valve member 30/55 and would be retained even in the axially collapsed state of Figure 2 (App. Br. 34). According to the Patent Owner, an advantage of the structure of the catheter of claim 19 is that the blood may only travel in tube 15 to the seal and never enters hub 11 even after the seal is opened by the luer connector 21 (*id.*).

Patent Owner's interpretation contrasts the language of claim 19, which does not recite the term "bloodless" and expressly requires a sealed relation "to prevent a flow of fluid from said cannula *to said proximal end of said hub*" (App. Br., Claim App'x 3) (emphasis added). We note that claim 19 does not expressly recite that fluid be prevented from leaving the tube or cannula. We find that Vaillancourt '766's valve member 55 prevents fluid from reaching the proximal end of the hub, and Patent Owner does not argue otherwise.

Claim 27

Claim 27 depends from claim 1 via claims 6 and further states that a "first means [i.e., a tube] extends from said cannula to said seal" (App. Br., Claim App'x 5). The Examiner finds that, as shown in Figure 2, when axially collapsed, inner tube 20 extends from valve member 55 to cannula 19 (ACP 22).

As with claim 7 and 8 above, Patent Owner's arguments are based on Figures 1 and 3 in which the luer adaptor 40 has not yet been applied (App. Br. 36).

Again, it is reasonable to find that the claim 27 reads on the valve member when the luer adaptor 40 is inserted into hub 10, as illustrated in Figure 2, when a tubular portion of valve member 55 receives tube 20. We discern no reason to

interpret the requirements of claim 27 to exist only when no luer adaptor is present, and Patent Owner has provided no evidence or reasoning for us to do so.

Claim 29

Claim 29 depends from claim 19 and further requires that the "seal is sealed in an interference fit manner to said bore of said hub, said interference fit determining the maximum pressure allowable in said catheter before leakage into said proximal end of said hub occurs" (App. Br., Claim App'x 5).

Patent Owner contends that Vaillancourt '766 does not disclose that there is any interference fit that determines the maximum pressure allowable in the catheter before leakage into the proximal end of the hub occurs (App. Br. 45). The Examiner finds that Vaillancourt '766 teaches an "interference fit that would determine the maximum pressure allowable prior to leakage" (ACP 22-23).

We agree with Patent Owner that Vaillancourt '766 does not expressly disclose a relationship between the "interference fit" of the valve member 55 and the maximum pressure allowable before leakage. However, we agree with the Examiner that the relationship is inherently disclosed in Vaillancourt '766.

Vaillancourt '766 teaches that blood spillage is prevented by the open support end of valve member 55 engaging the side wall of the catheter hub, which "seals off the insert inlet end from the entrance to the catheter hub" (Vaillancourt '766, col. 2, ll. 53-56). In other words, Vaillancourt '766 teaches that the interference fit is what prevents blood leaking from the distal chamber 33 to the proximal chamber 11. We agree with the Examiner that the interference fit taught by Vaillancourt '766 necessarily dictates the maximum pressure at which blood

would leak around the valve member 55. Patent Owner has directed us to no persuasive rationale or evidence to undermine this reasoning.

SUMMARY

We affirm the following rejections:

1. Claims 1-3, 6, 23, and 25 under 35 U.S.C § 102(b) as anticipated by Cox (see Rejections 1 and 31).

2. Claims 1-3, 6, 22, 23, and 25 under 35 U.S.C. § 103(a) as obvious over Cox (see Rejections 2 and 30)

3. Claims 1-3, 6, 16, 24 and 26 under 35 U.S.C. § 103(a) as obvious over Cox in view of Sylvanowicz (see Rejections 3 and 32).

4. Claim 17 under 35 U.S.C. § 103(a) as obvious over Cox in view of Fischell.

5. Claims 1, 3, 6, 13, 14, and 18 under 35 U.S.C § 102(b) as anticipated by Luther.

6. Claims 1, 3, 6, 10-13, 14, and 18 under 35 U.S.C. § 103(a) as obvious over Luther.

14. Claims 1-3, 6, 10-15, and 20 under 35 U.S.C. § 103(a) as obvious over Van Heugten in view of Luther.

16. Claims 1-4, 6- 9, 15, 19, 27-30 under 35 U.S.C. § 103(a) as obvious over Vaillancourt '766 (see Rejections 16 and 34).

17. Claims 1-9, 15, and 19under 35 U.S.C. § 103(a) as obvious over Vaillancourt '766 in view of Vaillancourt '891.

26. Claim 21 and 33 under 35 U.S.C. § 103(a) as obvious over Van Heugten in view of Luther and Vaillancourt '728.

36. Claim 31 under 35 U.S.C. § 103(a) as obvious over Vaillancourt '766 in view of Cox.

38. Claim 32 under 35 U.S.C. § 103(a) as obvious over Vaillancourt '766 in view of Cox and Sylvanowicz.

40. Claims 34 and 36 under 35 U.S.C. § 103(a) as obvious over Van Heugten in view of Luther and Cox.

41. Claim 35 under 35 U.S.C. § 103(a) as obvious over Van Heugten in view of Luther and Sylvanowicz.

42. Claim 37 under 35 U.S.C. § 103(a) as obvious over Van Heugten in view of Luther, Cox, and Sylvanowicz.

We reverse the rejection of claims 10-12 under 35 U.S.C § 102(b) as anticipated by Luther (*see* Rejection 5). We do not address the merits of the remaining Examiner's rejections, namely Rejections 7-13, 15, 20-25, 27, 28, and 33.

TIME PERIOD FOR RESPONSE

Requests for extensions of time in this *inter partes* reexamination proceeding are governed by 37 C.F.R. § 1.956. *See also* 37 C.F.R. § 41.79.

AFFIRMED

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY
Requester & Respondent

v.

MICHAEL J. VAILLANCOURT
Patent Owner & Appellant

Appeal 2012-003151
Reexamination Control 95/000,565
Patent 6,699,221 B2
Technology Center 3900

Before RICHARD M. LEBOVITZ, JEFFREY B. ROBERTSON, and RAE LYNN P. GUEST, *Administrative Patent Judges*.

GUEST, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

On July 27, 2012, Patent Owner and Real Party in Interest of U.S. Patent 6,699,221 B2 (hereinafter, "the '221 patent"), Michael J. Vaillancourt (hereinafter "Patent Owner"), requested rehearing under 37 C.F.R. § 41.79 of the Board's Decision of June 29, 2012, affirming the Examiner's rejections of claims 1-37 in an *inter partes* reexamination (hereinafter "Request"). Respondent and Third Party

Requester also filed Comments in response to Patent Owner's Request on August 27, 2012 in accordance with 37 C.F.R. § 41.79(c).

Patent Owner contends that the Decision misinterpreted the facts and law in its interpretation of certain identified terms and, based on this misinterpretation, erred in finding the claims anticipated by, or concluding that the claims are obvious over, the prior art (Request 1-2; *see also* Request 17-30 (discussing the claim interpretation with respect to each of the affirmed rejections)).

Claim 1 is reproduced below for convenience. (App. Br., Claim App'x 1.)

> 1. A bloodless catheter comprising
> a first hub having a bore at a proximal end;
> a cannula fixed in and extending from an opposite distal end of said hub for invasive positioning in a blood vessel; and
> a septum seal mounted in said bore of said hub in circumferentially sealed relation to prevent a flow of fluid from said cannula to said proximal end of said hub, said seal having a weakened central section.

CLAIM INTERPRETATION

During reexamination, "claims . . . are to be given their broadest reasonable interpretation consistent with the specification, and . . . claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (*quoting In re Bond*, 910 F.2d 831, 833 (Fed. Cir. 1990)).

Patent Owner's Request argues that the Decision erred in its interpretation of the following terms:

(a) "hub" as encompassing a structure having more than one piece (Request 9-11);

(b) "bore" as encompassing a structure having a recess formed within a hollow chamber or barrel (Request 11-13); and

(c) "septum seal" as encompassing a structure of the valve member 55 of Vaillancourt '766 (Request 13-16).

We are not persuaded that our interpretation of these terms was in error.

For each of the terms noted above, Patent Owner argues that the Decision ignores the plain language of the claims (Request 9:18, 11:20-21, 13:20-22). However, Patent Owner fails to disclose what aspect of the plain language would alter the interpretation provided in the Decision. The claims use the terms "hub," "bore" and "septum seal" with no qualifying language to further structurally define these features. That is, the claims do not expressly recite that a "hub" is limited only to structures having a one-piece body, that a "bore" may not have recesses therein, or that a "septum seal" be structurally limited to any particular shape.

Patent Owner argues that the inventor's descriptions in the Specification and drawings of the '221 patent constitute the broadest reasonable interpretation consistent with the Specification and that "the Board Decision gives no credence to the inventor's description" (Request 10:8-10 and 13-15, 12:3-12, 14:1-10).

The Decision acknowledged the use of the terms in the Specification in interpreting the claims (*see e.g.*, Decision 8, 19, and 32). The '221 patent provided no special meaning to the terms at issue, a point noted by Patent Owner in the Request (Request 10 and 11). *See In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007) ("During reexamination, as with original examination, the PTO must give claims their broadest reasonable construction consistent with the specification. Therefore, we look to the specification to see if it provides a definition for claim terms, but otherwise apply a broad interpretation.").

As aptly stated in *In re Morris*, 127 F.3d 1048, 1056 (Fed. Cir. 1997):

> The appellants urge us to consult the specification and some of the cited prior art . . . and interpret the disputed language more narrowly

> in view thereof. When read in light of this material, according to applicants, the "true" meaning of the phrase emerges. We decline to attempt to harmonize the applicants' interpretation with the application and prior art. Such an approach puts the burden in the wrong place. It is the applicants' burden to precisely define the invention, not the PTO's . . . .
>
> The problem in this case is that the appellants failed to make their intended meaning explicitly clear. Even though the appellants implore us to interpret the claims in light of the specification, the specification fails to set forth the definition sought by the appellants.

While claims are sometimes construed more narrowly during patent infringement litigation to do justice and equity between the parties, adopting the broadest reasonable interpretation while the claims are undergoing reexamination is not unfair to the applicant as the claims can be amended and so interpreting the claims "serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified," *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir.1984); *see also In re Prater*, 415 F.2d 1393, 1395-96 (CCPA 1969). We are, therefore, vigilant about not importing extraneous limitations into the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments."); *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) ("[L]imitations are not to be read into the claims from the specification.").

For example, with respect to the term "bore," Patent Owner argues that a recess in a bore would preclude the movement of the septum seal as demonstrated in Figures 3 and 4 of the '221 patent, and thus the Decision's broader interpretation of the term "bore" would be contrary to the disclosure (Request 12). We note that

the claims are silent as to the septum seal being capable of sliding in any particular manner, and we decline to read into the claims such a requirement.

Moreover, the Decision's broadest reasonable interpretations are not inconsistent with the Specification's embodiments. An interpretation is inconsistent with the Specification if the interpretation would exclude the specific embodiments described therein. Here, the panel's broader interpretation of the terms "hub," "bore," and "septum seal" encompasses not only the exemplified constructions described in the Specification but also other constructions that one of ordinary skill in the art would consider to be encompassed by the unqualified language of the claims. For example, with respect to the term "bore," we disagree with the Patent Owner's assertion that the Decision's interpretation "imposes a limitation that is not apparent in the language of the claim at issue, i.e., that the bore has a recess" (Request 12). To the contrary, the Decision's interpretation encompasses bores that have a recess and bores that do not have recesses because the unqualified term "bore" is not reasonably limited to any particularly shaped hollow structure. The written description of the '221 patent does not indicate that bores should be construed more narrowly to exclude recesses.

Patent Owner argues that the Decision failed to consider the citations to certain patents in the background section of the Specification, which Patent Owner alleges are examples of how one of ordinary skill in the art would have understood the terms at issue (10:3-5; 11:23-12:2, 14:11-15:7). With respect to the term "septum seal," Patent Owner further points to the use of terms in the inventor's other patents (Vaillancourt '891 an Vaillancourt '728), in which the term "septum" described only a part of a valve structure (Request 15 and 26-27), and statements made during prosecution of the '221 patent with regard to the Newgard reference

(US 4,874,377) (Request 16-17) as evidence of misinterpretation of the term "septum seal" as claimed.

While the Specification and prosecution history of the '221 patent may include reference to patents in the art, Patent Owner did not argue in the Specification, during reexamination prosecution, or during the appeal that the terms used in these references constituted the full scope of the terms of the claims. The Request for Rehearing is not a time to rely upon arguments and evidence that could have been raised earlier. 37 C.F.R. § 41.79(b)(1) (2009) ("Arguments not raised in the briefs before the Board and evidence not previously relied upon in the briefs are not permitted in the request for rehearing except as permitted by paragraphs (b)(2) and (b)(3) of this section."). Patent Owner provided no persuasive evidence on appeal that the noted claim terms deserve a more narrow meaning or that the references identified in the Specification or prosecution history limit how a skilled artisan would understand these terms. Moreover, it is not evident from reading the '221 patent that the patents cited in the specification, e.g., at col. 1, ll, 36-45, that the inventors intended to rely upon the cited patents to define and limit the structures recited in the claims at issue.

Moreover, we are not persuaded that the prior art patents teachings are evidence that one of ordinary skill in the art would have understood the term "septum seal" to have a more narrow meaning than the interpretation provided in the Decision. The prior art used the term "septum" and not "septum seal." Accordingly, the prior art has only limited weight as to the scope and meaning of the distinct term "septum seal" of the '221 patent's claims. For that reason, Patent Owner has not shown that the prior art's use of the term "septum" is inconsistent with the Decision's interpretation of the term "septum seal."

Further, Patent Owner has not sufficiently explained why the statements made regarding the Newgard patent during prosecution of the '221 patent "precludes the septum seal from being read as the valve member 55 of Vaillancourt '766 (i.e. as supported circumferentially at one end and extended into space at another end[])]" (Request 17). According to Patent Owner's description, the arguments were directed to the fact that Newgard's seal was not in "circumferentially sealed relation" because "there is a circumferential gap between obturator member 48 [the alleged seal in the Newgard patent] and the wall of the bore 42 of the hub 38" (*id.* at 16-17). Yet, unlike the Newgard seal, the valve member 55 of Figure 3 of Vaillancourt '766 has one end in a friction fit with the bore of the hub and, thus, is in a "circumferentially sealed relation" as claimed (*see* Vaillancourt '766, Figure 3; Decision 33-34).

Patent Owner further contends that it is erroneous to resort to a dictionary definition, which Patent Owner deems "extrinsic evidence," when intrinsic evidence can resolve an ambiguity of a disputed claim (Request 11) (citing *Vitronics Corp. v. Conceptronics, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

Our focus is properly directed to how one of ordinary skill in the art would have understood the unqualified terms "hub," "bore," and "septum seal." Accordingly, our resort to a dictionary definition as evidence of what a skilled artisan would have understood is proper. "Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005). Patent Owner

provided no persuasive evidence in its Appeal Brief as to how the skilled artisan would have understood the terms at issue and the Specification provides no express definition. Accordingly, the panel's reliance on dictionary definitions to determine the broadest reasonably interpretation to the skilled artisan is appropriate.

We cannot agree that the Decision's interpretation of the terms "hub," "bore," and "septum seal" was unreasonably broad, and we do not alter the Decision's interpretation. Accordingly, we need not address Patent Owner's arguments of patentability based on a more narrow interpretation. However, we address Patent Owner's additional arguments directed to specific claims and rejections below.

With respect to claim 10, Patent Owner contends that Figures 2 and 3 of Luther illustrate that "the front end of the plug [35b] slides relative to the surface of the septum [33]" which precludes the plug 35b from being "mounted on the septum [33]" (Request 20 and 23). According to Patent Owner, if mounted, "a relative movement between the plug and septum would be resisted and/or the movement of the plug would cause a tearing of the septum" (*id.*). With respect to claim 20, Patent Owner likewise contends that the Decision failed to apprehend that opener 120 of Van Heugten would not deform the membrane 110 if it were mounted thereon (Request 23-24).

The arguments made in the Appeal Brief with respect to claim 10 are not directed to any movement implied by Figures 2 and 3 of Luther (*see* App. Br. 17-18 and 20). As noted in the Decision, and thus not overlooked or misapprehended, Patent Owner's arguments regarding the rejection based on Luther were directed to a membrane opener 120 and a membrane 110, which do not appear in Luther

(Decision 21; App. Br. 20). We decline to address arguments made for the first time upon rehearing. 37 C.F.R. § 41.79(b)(1).

Moreover, also as noted in the Decision:

> Further, Patent Owner has directed us to no evidence in support of the contention that the plug 35b or opener 120 would not function if "mounted," or supported, by the respective seals of Luther and Van Heugten. Attorney arguments do not take the place of evidence in the record. *Pearson*, 494 F.2d at 1405.

(Decision 26.) Accordingly, the Decision considered Patent Owner's arguments and found them not persuasive for lack of evidence in support thereof.

Patent Owner further argues that Van Heugten fails to disclose valve member 110 in circumferentially sealed relation to the bore (Request 22-23).

As stated in the Decision:

> Regarding the septum seal being in circumferentially sealed relation to the bore, Patent Owner merely asserts that these claim features are not taught by Van Heugten (*id.*). A general allegation that the art does not teach the claim limitations is no more than merely pointing out the claim limitations. *See* 37 C.F.R. § 41.67(c)(1)(vii). In any event, such statements do not address the Examiner's specific findings and support therefore (*see* ACP 12, citing Van Heugten, col. 1, ll. 4-27, col. 2, ll. 45-50, col. 3, l. 59-col. 4, l. 49, and Figures 2, 3, and 4a-4c) articulated in the rejections or explain why the Examiner's findings are not supported by the evidence.

(Decision 23.) The arguments made in the Request address the merits of the Examiner's findings for the first time upon rehearing, which is not appropriate. 37 C.F.R. § 41.79(b)(1).

With respect to claim 4, Patent Owner further contends that "[t]he fact that the valve member 55 of Vaillancourt '766 collapses axially precludes an

interpretation that the valve member 55 is slidably mounted in the bore of the hub 10" (Request 28).

Upon Rehearing, Patent Owner must "must state with particularity the points believed to have been misapprehended or overlooked in rendering the Board's opinion reflecting its decision." 37 C.F.R. § 41.79(b)(1).

The Decision states that:

> Patent Owner's arguments focus on the fact that the various portions of valve member 55, i.e., support end 56, valve end 31, and the thin-walled section 54, individually cannot meet the requirements of claim 4. However, Patent Owner fails to address the fact that the Examiner finds the mounting and axial movement of valve member 55, as a whole, meets the requirements of the claim 4. Accordingly, we are unconvinced that the Examiner's position, which is based on sufficient rational underpinnings, is improper.

(Decision 35.) Patent Owner directs us to no points that the Decision misapprehended or overlooked. Patent Owner has not shown the reasoning provided in the Decision to be untenable.

Finally, with respect to claim 7, Patent Owner contends that "the Examiner cannot reasonably find that claim 7 reads on the valve member when the luer adaptor 40 is inserted into the hub 10, as illustrated in Fig. 2, when the valve member 55/30 is axially collapsed onto tube 20" (Request 29).

Again, Patent Owner has not identified the points believed to have been misapprehended or overlooked in the Decision. 37 C.F.R. § 41.79(b)(1). The Decision states that:

> The Examiner reasonably finds that the claim 7 reads on the valve member when the luer adaptor 40 is inserted into hub 10, as illustrated in Figure 2, when valve member 55/30 is axially collapsed onto, and thus supported by, tube 20. We see no reason to read the requirements of claim 7 to exist only when no luer adaptor is present,

> and Patent Owner has provided no evidence or reasoning for us to do so.

(Decision 36). Patent Owner has not shown the reasoning provided in the Decision to be untenable.

Based on the foregoing, we have granted Patent Owner's request to the extent that we have reconsidered our decision, but we deny Patent Owner's request to alter our decision to affirm the Examiner's rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. §1.136(a)(1)(iv).

DENIED

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US006699221B2

(12) **United States Patent**
Vaillancourt

(10) **Patent No.: US 6,699,221 B2**
(45) **Date of Patent: Mar. 2, 2004**

(54) **BLOODLESS CATHETER**

(76) Inventor: **Vincent L. Vaillancourt**, 14 Bunyan Dr., Livingston, NJ (US) 07039

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/879,872**

(22) Filed: **Jun. 12, 2001**

(65) **Prior Publication Data**

US 2001/0053895 A1 Dec. 20, 2001

Related U.S. Application Data

(60) Provisional application No. 60/211,733, filed on Jun. 15, 2000.

(51) **Int. Cl.**[7] **A61M 5/178**

(52) **U.S. Cl.** **604/167.01**; 604/167.03; 604/167.04; 604/167.06; 604/164.13

(58) **Field of Search** 604/167.01, 167.04, 604/167.02, 167.03, 167.06, 171, 164.01, 164.07, 164.13

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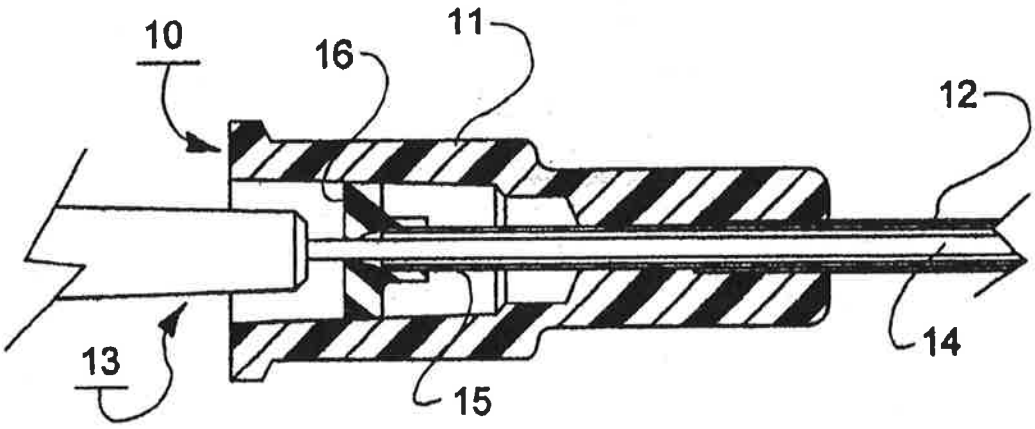
* cited by examiner

Primary Examiner—Brian L. Casler
Assistant Examiner—Jeremy Thissett
(74) *Attorney, Agent, or Firm*—Francis C. Hand; Carella, Byrne, Bain et al.

(57) **ABSTRACT**

The over-the-needle catheter is provided with a septum seal within the hub of the catheter. The introducer needle passes through the septum seal and into the catheter. Upon removal of the introducer needle, the septum seal reseals so that blood is prevented from flowing from the patient out of the hub. A male luer adaptor is used to form a connection, for example, to an IV bag by pushing the seal onto a tube secured within the hub and communicating with the catheter or, in another embodiment, by pushing a piercing ring through a slit in the septum seal to form a permanent lumen.

20 Claims, 5 Drawing Sheets



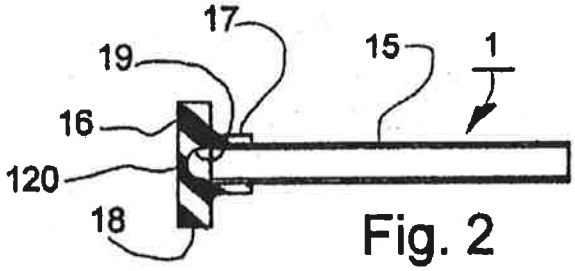


Fig. 2

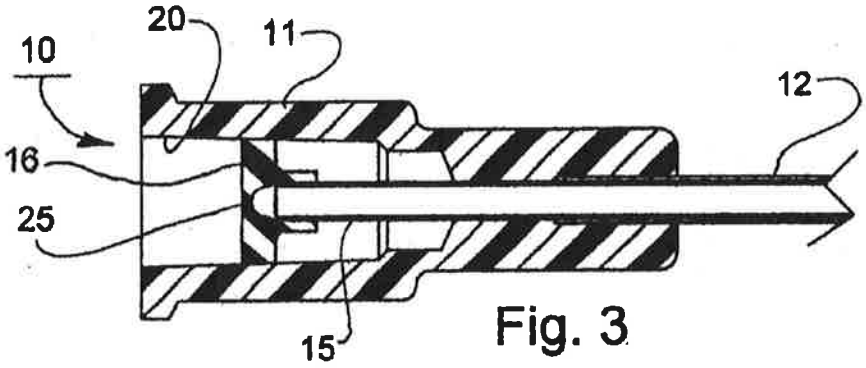


Fig. 3

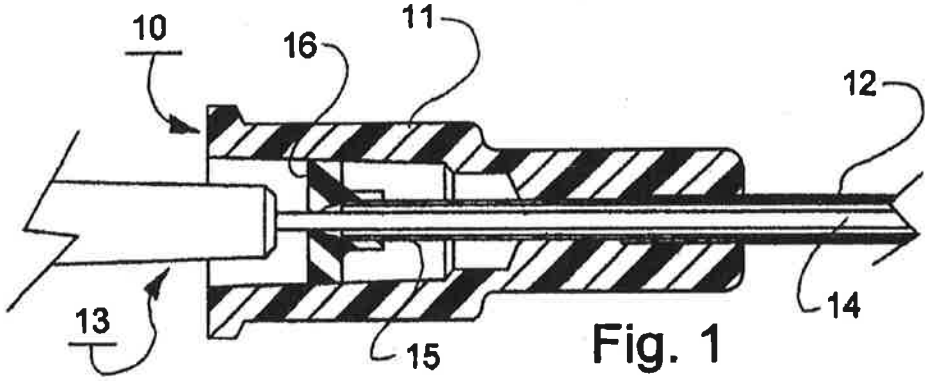


Fig. 1

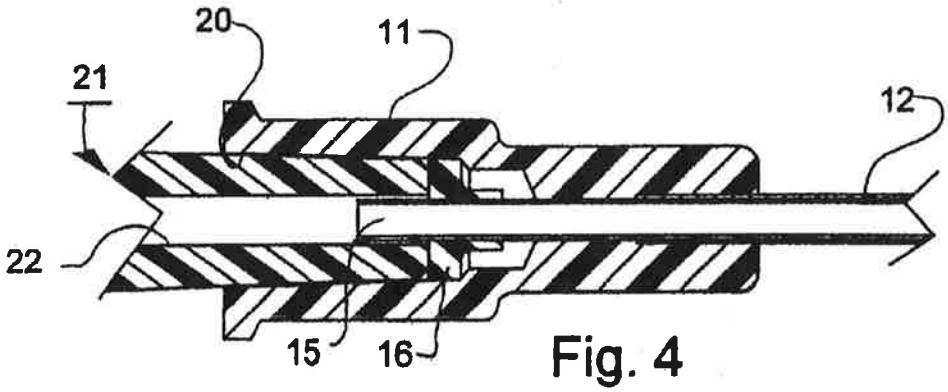


Fig. 4

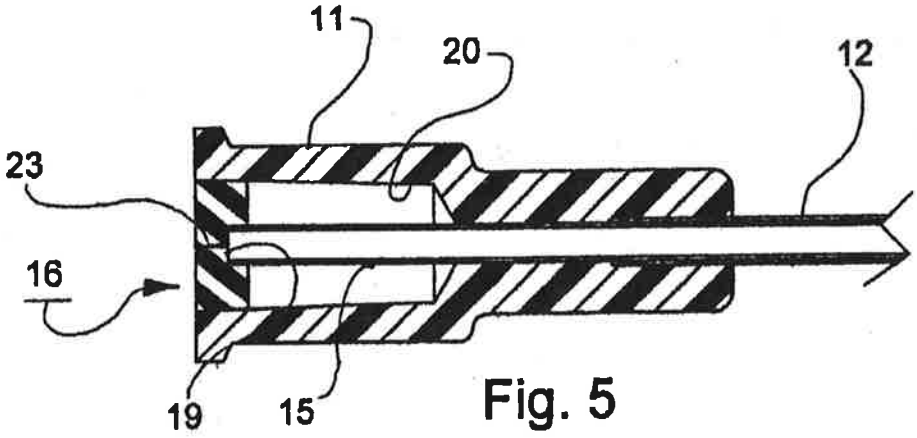


Fig. 5

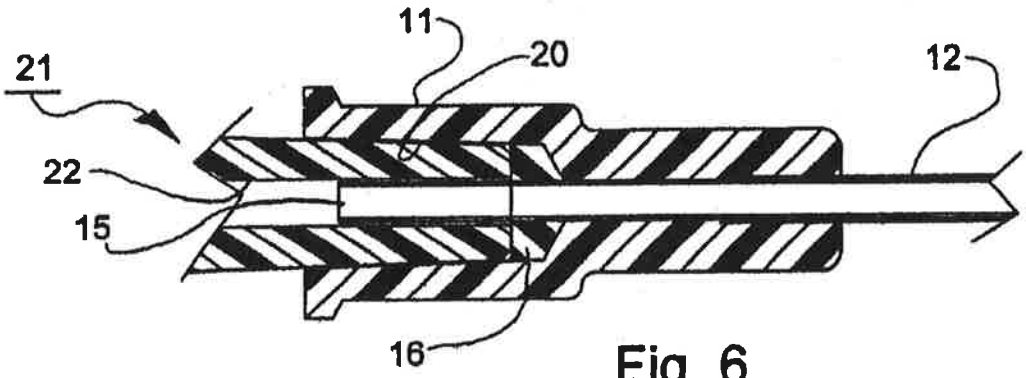


Fig. 6

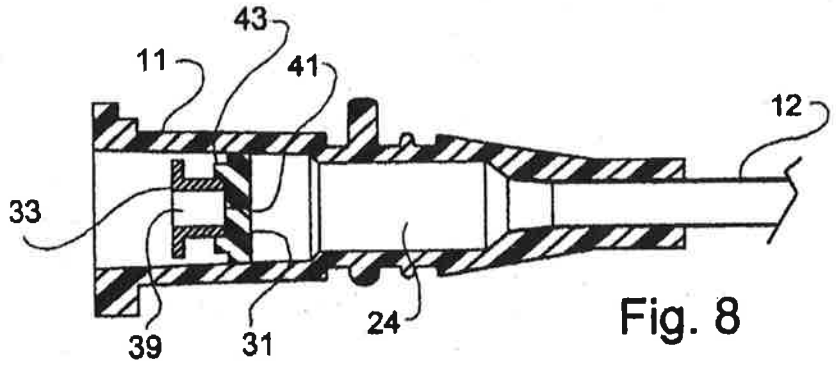


Fig. 8

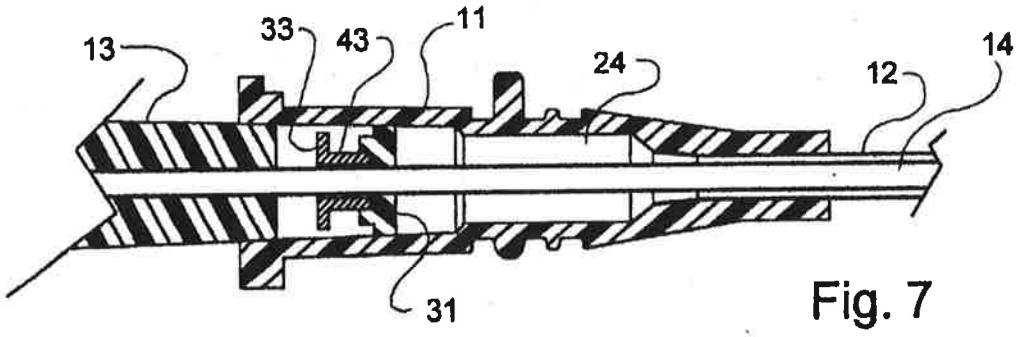


Fig. 7

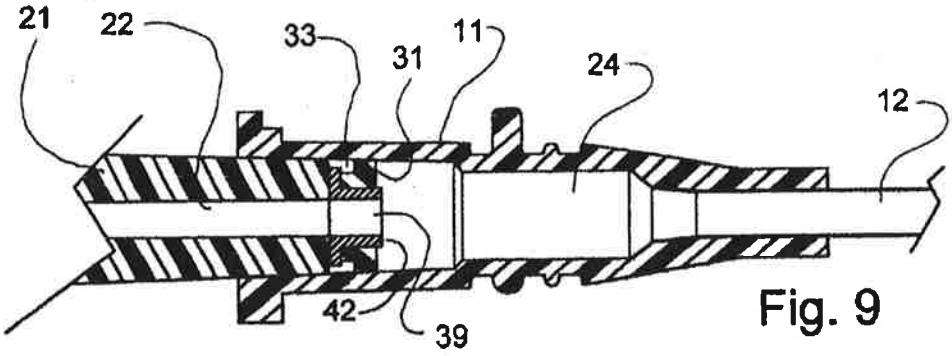


Fig. 9

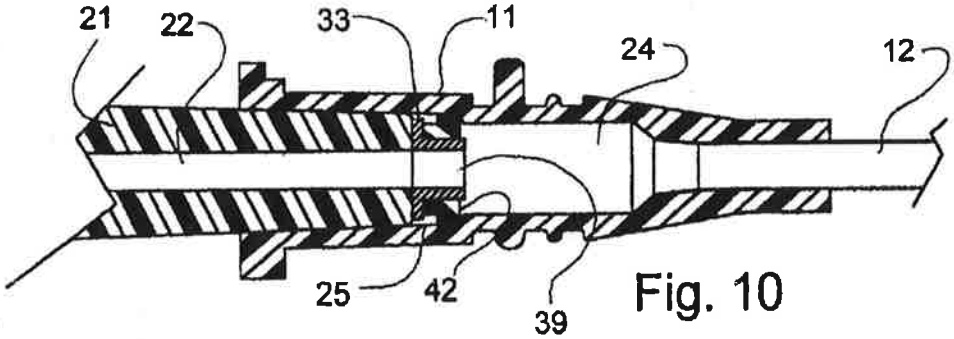


Fig. 10

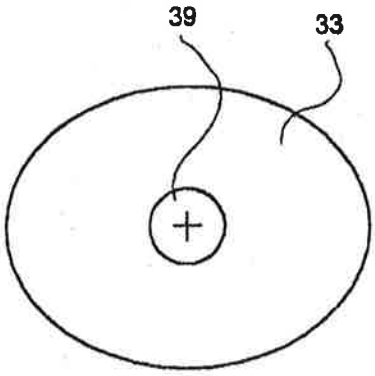


Fig. 11

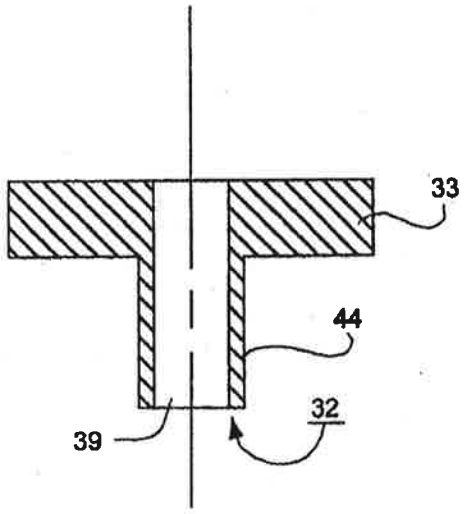


Fig. 12

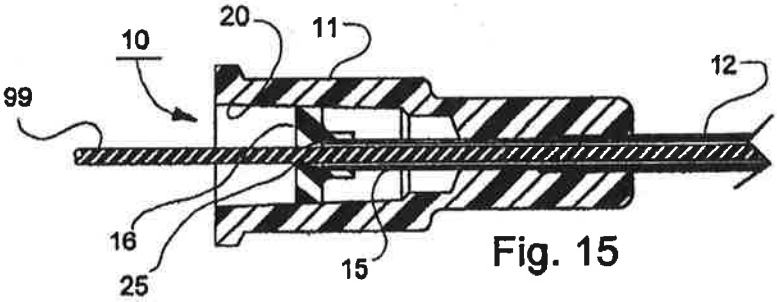


Fig. 15

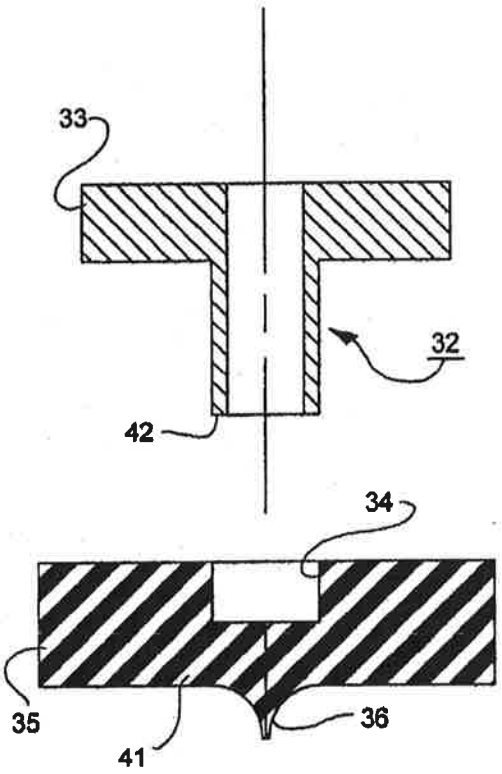


Fig. 13

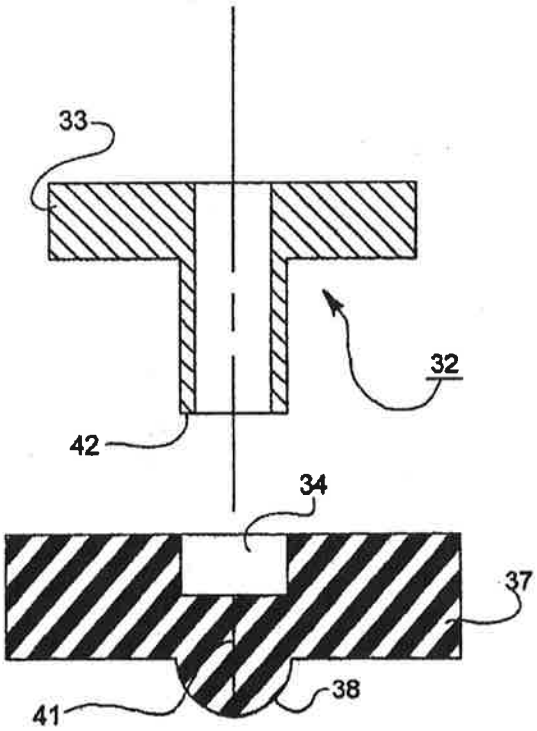


Fig. 14

BLOODLESS CATHETER

This application claims the benefit of U.S. Provisional Application 60/211,733, filed Jun. 15, 2000.

This invention relates to a bloodless catheter. More particularly, this invention relates to a bloodless over-the-needle catheter.

Various types of over-the-needle catheters have been known for use as venipuncture devices and, particularly, for intravenous infusion purposes. Typically, these devices have been fabricated of a needle that is connected to a hub and a catheter that passes over the needle and is fixed as by a friction fit at an exposed end of the needle. The catheter is also fixed to a hub that receives the needle hub. Additional structure is also provided to form a closed chamber about the ends of the two hubs.

After implanting of the needle and catheter in a patient, the needle is usually removed while the catheter remains in place. A connection is then made between an I.V. line and the catheter in order to allow for the infusion of liquids and/or medicaments into the patient.

In almost all hospitals, there is a policy that once a catheter is in place and a connection made, that connection is never broken. With that as a design criteria, then there is no need for a bloodless catheter to have a reseal capability beyond the initial closure following the removal of the needle. In other words, there is a need only for the hub to somehow seal itself off from the outside environment when the needle is removed and then re-opened to allow fluid flow when a connection is made, e.g. by means of a male luer connector. The male luer connector is attached only once and never removed from the catheter hub. If per chance the male luer connector has to be removed in an emergency situation, then it would be permissible for blood to back flow through the catheter.

U.S. Pat. Nos. 5,330,435 and 5,234,410 describe different types of over-the-needle catheters which employ an elastomeric valve on a tube of the catheter to seal off the cannula of the catheter.

U.S. Pat. No. 5,211,634 describes a composite seal structure which is used in a coupling between a syringe and a line to a vein in a patient.

U.S. Pat. No. 5,487,728 describes the use of a seal having a resilient collapsible tubular portion and a septum at one end for sealing off a needle in a female luer connector.

Accordingly, it is an object of the invention to provide product which would meet these needs and be substantially less complicated, less costly to make and assemble than the previously known products.

Briefly, the invention is directed to a bloodless catheter comprised in part of a hub having a bore at a proximal end and a cannula fixed in and extending from an opposite distal end of the hub.

In accordance with the invention, a septum seal with a weakened central section is mounted in the bore of the hub in circumferentially sealed relation to prevent a flow of fluid from the cannula to the proximal end of the hub.

A means is also provided in the hub for forming a flow path through the weakened section of the seal in response to a relative movement between this means and this seal.

In use, a second means is provided for moving the first means relative to the seal in order to define a flow path through the seal.

In one embodiment, the means in the hub for forming a flow path is in the form of a tube which is mounted in the weakened section of the seal and which extends into the cannula. In addition, the means for moving the tube relative to the seal constitutes a male luer adaptor which can be slidably mounted in the bore of the hub in sealed relation and disposed concentrically about the tube. In this case, the forward end or nose of the adaptor engages and pushes the septum seal along the tube while the seal dilates about the slit in the weakened section of the seal.

In this embodiment, after the introducer needle and associated hub have been removed, the seal prevents any flow of blood from a patient through the hub.

In another embodiment, the means for forming a flow path through the weakened section of the seal is in the form of a piercing ring that is mounted on the seal for pushing through the weakened section of the seal in a direction towards the cannula in order to define a flow path through the seal. In this embodiment, a male luer adaptor may also be used as the means to move the piercing ring relative to the seal. In this case, the male luer adaptor is sized to engage and push the piercing ring through a slit in the septum seal in order to communicate the adaptor with the cannula.

Typically, in order to form an over-the-needle catheter, a needle hub is telescopically mounted in the bore of the hub while an introducer needle is fixed in the needle hub and extends through the cannula. In use, the introducer needle and catheter are introduced into a patient in the usual manner. Thereafter, the introducer needle and associated hub are withdrawn. At this time, the seal closes on itself to seal off the cannula from the proximal end of the first hub so that blood cannot flow from the patient out of the hub.

These and other objects and advantages of the invention will become more apparent from the following detailed description taken in conjunction with the accompanying drawings wherein:

FIG. **1** illustrates a cross-sectional view of a product constructed in accordance with the invention for use as an over-the-needle catheter;

FIG. **2** illustrates a cross-sectional view of a seal and tube arrangement used in the product of FIG. **1** in accordance with the invention;

FIG. **3** illustrates a view similar to FIG. **1** with the introducer needle removed;

FIG. **4** illustrates a view similar to FIG. **3** of the product connected to a male luer connector in accordance with the invention;

FIG. **5** illustrates a cross-sectional view of a modified product having a modified seal located at an open end of a catheter hub in accordance with the invention;

FIG. **6** illustrates a view similar to FIG. **5** of the modified product connected to a male luer connector in accordance with the invention;

FIG. **7** illustrates a cross-sectional view of a second embodiment of an over-the-needle catheter employing a seal and piercing ring in accordance with the invention;

FIG. **8** illustrates a cross-sectional view of the embodiment of FIG. **7** with the catheter and associated hub removed;

FIG. **9** illustrates a view similar to FIG. **8** with a male luer partially inserted in the hub;

FIG. **10** illustrates a view similar to FIG. **9** with the male luer adaptor secured within the hub;

FIG. **11** illustrates a top view of a piercing ring constructed in accordance with the invention;

FIG. **12** illustrates a side view of the piercing ring of FIG. **11**;

FIG. **13** illustrates an exploded view of the piercing ring of FIG. **12** with a modified seal with a duck bill configuration in accordance with the invention;

FIG. **14** illustrates an exploded view of the piercing ring of FIG. **12** with another modified seal with a bullet configuration in accordance with the invention; and

FIG. **15** illustrates a cross-sectional view of the catheter with a guide wire extending through the seal.

Referring to FIG. **1**, the product **10** is constructed in the manner of an over-the-needle catheter with a hub **11**, a cannula **12**, e.g. a needle with a sharpened tip, made of metal or plastic, which is fixed in and which extends from the hub **11**, a needle hub **13** and an introducer needle **14** which is fixed in the needle hub **13** and which extends coaxially through the cannula **12**. The distal end of the needle **14** extends through the distal end of the cannula **12** and is secured thereto in a friction fit manner as is known. The construction of the hubs **11**, **13**, cannula **12** and needle **14** are conventional and need not be further described.

The product **10** also has a tube **15**, for example of metal, which is secured internally within the catheter hub **11** and on which a septum seal or adaptor **16**, for example of an elastomeric material is mounted. As indicated, the tube **15** is fixed within the catheter hub **11** and extends to a point within the plastic cannula **12**. The tube **15** is otherwise of a size to permit passage of the needle **14**.

Referring to FIG. **2**, the septum seal **16** is of generally T-shaped construction having a tubular portion **17** which fits over the tube **15** in a stretch-fit manner. In addition, the seal **16** has a cap **18** integral with the tubular portion **17**. This cap **18** has an internal recess **19** which defines, in part, a weakened section **120** of the cap **18** within which a slit (not shown) may be formed to function as a valve. The seal **16** is placed over the tube **15** in an interference condition. Prior to this operation, the seal **16** is pierced to form a slit through which the needle **14** passes or alternately may be pierced directly by the needle **14**. The purpose of the seal **16** to tube **15** seal (interference fit) is to prevent fluid from entering the space distal to the location of the seal **16**.

The seal **16** is larger in diameter than the hub wall where the seal **16** is positioned is compressed thereby forming a pressure seal around the needle **14**. In one example, the tube **15** has an outside diameter of 0.045", the tubular portion **17** of the seal **16** has an inner diameter of 0.037" and the cap **18** of the seal **16** has an outer diameter of 0.165" and a length of 0.040". In the sealed position, the hub wall where the seal **16** is positioned is of a diameter of 0.155". The compression on the seal **16** is thus 0.010" or approximately 6%. Under these conditions, the leakage pressure exceeds 10 psi.

Referring to FIG. **1**, the seal **16** is located in a recessed manner within a tapered bore **20** of the hub **11** and is disposed in a circumferentially sealed relation, e.g. in an interference fit manner to the bore **20** of the hub **11** to prevent a flow of fluid from the cannula **12** to the proximal end of the hub **11**.

As shown in FIG. **1**, the needle **14** passes through the cap **18** of the seal **16** in a seal tight manner.

The interference fit between the seal **16** and the hub **11** is such that when the needle **14** is withdrawn, the seal **16** closes providing a leak proof seal to any blood which may pass back up through the catheter **12**. The seal between the seal **16** and the tube **15** is sufficient to prevent fluid (blood) from exiting the tube **15** and passing into the space adjacent to the tube **15** within the catheter hub **11**.

The interference fit between the cap **18** of the seal **16** and the bore **20** of the catheter hub **11** determines the maximum pressure allowable in the catheter **12** before leakage into the proximal end of the hub **11** occurs.

The tube **15** functions as a means in the hub for forming a flow path through the weakened section **120** of the septum seal **16** in response to a relative movement between the tube **15** and the seal **16**.

A means is also provided for moving the tube **15** relative to the seal **16**. For example, this means may be in the form of a male luer connector **21**.

Referring to FIG. **4**, the product **10** may be connected to an I.V. line, for example, via a male luer connector **21** having

an internal bore **22** of a size to slide over the tube **15**. As indicated in FIG. **4**, when the male luer connector **21** is slid into the catheter hub **11**, the nose of the male luer connector **21** pushes the seal **16** into the interior of the hub **11** while sliding the seal **16** along the tube **15**. During this time, the weakened section **120** of the cap **18** of the seal **16** expands radially so as to move about the open end of the tube **15**.

After pushing the seal **16** over the tube **15** and down to the base of the catheter hub **11**, the male luer connector **21** bottoms against the seal **16** as shown in FIG. **4**, while dilating over the open end of the cannula **12**. As shown in FIG. **4**, a path for fluid flow is thus defined between the male luer connector **21** and the cannula **12**. This path is not restrictive and is straight through with no significant decrease in cross section.

A seal is thus created between the septum seal **16** and the nose of the male luer connector **21** obviating the necessity for the male luer taper having to create an interference fit with the female luer taper of the hub **11** to effect a seal. In this manner, normal luer connector tolerances are not required with regard to the hub **11** (female luer connector) in order to obtain an effective seal to a conventional male luer connector.

This is a one time use seal. By this is meant that upon assembly with the seal **16** sitting on top of the tube **15** and the needle **14** penetrating the face wall of the seal **16**, there is a seal between the needle **14** and seal **16**. Upon removal of the needle **14**, the opening created is closed due to the compressive action of the interference fit of the seal cap **18** and wall of the hub **11**. When the male luer connector **21** is connected to the hub **11**, the seal **16** is forced over the tube **15** permanently creating a through hole which is always larger than the tapered bevel portions of the (not shown) lumen of the cannula **12** to which the hub **11** is attached. Upon removal of the male luer connector **21**, the seal **16** remains in place and the cannula **12** continues to be in fluid communication with the proximal portion of the hub **11**.

Another advantage of the construction is the elimination of the need for the practitioner to apply digital pressure to the catheter **12** upon removal of the needle **14** from the catheter assembly. The elimination of this requirement in the catheterization procedure changes the procedure from one requiring extreme hand and finger dexterity to one that can easily be performed by a person who has normal skill. It has been long recognized that venipuncture using an over-the-needle catheter requires above average skill and much practice. As a result, many hospitals only allow certain nurses adept and trained in this art to perform these procedures. In some quarters, the procedure is referred to as a "three handed procedure" whereas only two hands are available.

Another advantage of the construction is the isolation of the blood from within the catheter hub **11**. The blood may only travel up the tube **15** to the seal **16** where a seal is affected. Thus, there is never any blood within the hub **11** even after the seal is opened by the male luer connector **21**. Any blood that may enter a portion of the tube **15** is immediately swept back into the blood vessel upon the initiation of flow upstream from the male luer connector **21**.

When the male luer connector **21** is engaged with the hub **11** (female luer), the dead space is the annular volume between the top of the luer lumen and the outer diameter of the tube **15**. This space is initially filled with fluid coming from the male luer connector **21** and, in most cases, does not exceed a micro drop of fluid. Thus, there is never any patient's blood in the hub **11** where the blood may stagnate, form a clot and eventually return to the blood vessel.

Referring to FIG. **5**, wherein like reference characters indicate like parts as above, the seal **16'** is constructed as a simple "septum" positioned at the entrance to the hub **11** (female luer adaptor). In this embodiment, the seal **16'** is in

the form of a disk having a tapered outer periphery, a weakened section defined by a coaxial recess **19'** on one side to receive the tube **15'** and a slit **23** centrally of the recess **19'** to act as a valve. As shown, the tube **15'** is elongated and has a tapered end to fit into the recess **19'** of the seal **16'** in a seal-tight manner.

Referring to FIG. **6**, wherein like reference characters indicate like parts as above, when a connection is desired, the nose of a male luer connector **21** pushes the "septum" **16'** along the outside of the tube **15'** while the central portion of the seal **16'** opens radially about the slit **23** allowing the connector **21** to slide over the tube **15'**. A fluid flow path is thus effected from the connector **21** into the tube **15'** and, thus, the cannula **12**. This is a one time use since the seal **16'** will not return to reseal once the seal **16'** has been bottomed by the male luer connector **21**.

The advantages of this construction include the ability to swab the face of the seal **16'** thereby rendering the face sterile prior to connection and simplicity of manufacture. The product of this construction can be readily used as a female portion of the connector of the product of U.S. Pat. No. 5,122,123 to complete an inexpensive one time use sterile coupling.

Other uses include the use of the seal and tube in the hub of an introducer needle for catheter procedures, guide wires, and the like. In these cases, when the needle is removed, blood continues to be contained. A guide wire may be passed down through the seal slit (hole) which being an elastomeric structure will give sufficiently to allow passage of the guide wire and concurrently effect a seal with the guide wire to prevent blood flow. Upon removal of the introducer needle, the external skin of the patient behaves as a secondary seal until the procedure (Seldinger) is completed. In like manner, the sealed hub can be used for placement of spinal needles prior to infusion generally of pain control drugs or removal of CSF (cerebral spinal fluid).

The embodiment of FIGS. **1** to **4** corresponds to a product known as a bloodless catheter in which the blood does not exit the hub **11** when the introducer needle **14** is removed. The embodiment of FIGS. **5** and **6** corresponds to a product known as a swabable valve connector, the advantage of which is that it can be rendered sterile by swabbing prior to coupling (connection). This is ideally suited for one time use with a sterile connector as described in U.S. Pat. No. 5,122,123. Either basic construction may be used with the usual applications for spinal, central lines (Seldinger), and the like.

Referring to FIG. **8**, wherein like reference characters indicate like parts as above, the bloodless catheter may be made such that a septum seal **31** is positioned in the bore **24** of a catheter hub **11** in circumferentially sealed relation just prior to inserting an introducer needle assembly **12, 13** (FIG. **7**). As indicated, the seal **31** has a centrally located weakened section defined by a slit **41** that defines a valve and the outer diameter of the seal **31** is sized to be larger than the inner diameter of the bore **24** of the hub **11** such that a compressive force is exerted on the internal portion of the seal **31** so that the slit **41** is closed.

In addition, a means in the form of a piercing ring **32** is mounted in the hub **11** on the seal **31** on the side facing the distal end of the hub **11** for forming a flow path through the weakened section **41** in response to a relative movement between the ring **32** and the seal **31**.

As shown in FIG. **12**, the piercing ring **32** has a flange **33** at one end and a tubular portion **44** that defines a central bore **39**. As shown in FIG. **11**, the flange **33** is of elliptical shape.

As shown in FIG. **8**, the tubular portion **44** of the piercing ring **32** is positioned within a recess defined by an annular shoulder **43** on the seal **31** and is frictionally held in place in alignment with the slit **41**.

Referring to FIG. **7**, the introducer needle assembly includes a hub **13** that is insertable in the catheter hub **11** and an introducer needle **14** that passes through the piercing ring **32** in spaced relation, through the slit **41** in the seal **31** in seal tight manner and through the cannula **12**. The slit **41** is opened by the sharpened end of the introducer needle **14** as the needle **14** passes through the seal **31** and into the cannula **12**. The bloodless catheter is supplied to a user in this condition prior to use.

After a venipuncture or arterial puncture is made and the introducer needle **14** and cannula **12** placed in a patient, the introducer needle **14** and associated hub **13** are removed. The seal **31**, being under a compressive force due to the interference of the wall of the bore **24** with the larger diameter of the seal **31**, then seals off the hub **11** in a manner as indicated in FIG. **8** so that blood is prevented from flowing from the patient and the bore **24** out of the hub **11**.

Referring to FIG. **9**, a hook-up to an IV bag (not shown) is performed by inserting a means such as a male luer adaptor (connector) **21** into the female luer catheter hub **11**. As the male luer adaptor **21** enters the bore **24** of the hub **11**, the flange **33** of the piercing ring **32** is encountered. The adaptor **21** then pushes the piercing ring **32** forwardly causing the tubular portion **44** to open the slit **41** in the seal **31** to thereby create a permanent lumen (opening) through the seal **31**. The resistance to the piercing ring **32** going through the slit **41** is less than the resistance of the septum seal **31** against the side wall of the bore **24**.

When the piercing ring **32** has bottomed out within the septum seal **31**, the ring **32** and seal **31** composite now move forwardly upon the application of further force by the male adaptor **21** until an interference fit is obtained between the male adaptor **21** and the bore **24** of the hub **11** as indicated in FIG. **10**. A connection is now effected and fluids may move from the IV bag through the cannula **12** and into the patient.

It is not necessary that the septum seal **31** be positioned as shown and moved during the connection process. The septum seal **31** and piercing ring **32** may be permanently positioned at a deeper location within the hub **11**. In this instance, the tubular portion **44** of the ring **32** would be longer to provide for tolerances encountered as stated in the ANSI/ISO/AMMI specifications for luer connectors.

The piercing ring **32** may be metallic or plastic. The elliptical shape of the flange **33** is to ensure that a portion of the nose **25** of the adaptor **21** is contacted during engagement of the adaptor with the ring **32**. Most male luer adaptors have an internal lumen of 0.100 inches or less. However, some have lumens as large as 0.125 inches. To provide for these lumens and the tolerances normally encountered in commercial luer connectors, it has been found that a somewhat elliptical piercing ring flange **33** will meet these requirements. In most cases, a circular piercing ring flange is acceptable. Other configurations, such as a bar laying across the tubular portion are acceptable.

In one embodiment, the septum seal of FIG. **8** was made of silicone having a Durometer of D-50. However, other elastomeric materials and durometers may be used. The seal also had a diameter of 0.175 inches with a thickness at the catheter hub wall of 0.090 inches. The recess defined by the shoulder **43** was 0.040 inches in diameter with a depth of 0.050 inches.

The flange **33** of the piercing ring **32** had a major diameter of 0.145 inches while the tubular portion **44** had a length of 0.100 inches and an outer diameter of 0.045 inches.

The catheter hub bore **24** had a diameter of 0.160 inches at the location where the septum seal **31** was initially positioned.

When positioned within the septum seal **31**, the interference fit between the ring **32** and the seal **31** was sufficient to hold the ring **32** in place with no concern that the ring would accidentally be dislodged.

After removal of the introducer needle **14** and pressure testing, it was found that the leakage pressure of a configu-

ration as shown in FIG. **8** exceeded 20 psi. Under similar conditions but with a septum seal having a duck bill configuration **36** as shown in FIG. **13**, the leakage pressure was 50% higher. Also, with a septum seal having a bullet configuration **38** as shown in FIG. **14**, the leakage pressure was even higher.

Referring to FIG. **15**, wherein like reference characters indicate like parts as above, a guide wire **99** or a stylet (not shown) or the like may be passed through the weakened section of the seal **16** and into and through the cannula for insertion into a blood vessel of a patient in a conventional manner. Upon withdrawal of the wire **99**, the seal **16** closes to seal off the hub **11**.

The invention thus provides an over-the-needle product for making a bloodless venipuncture or arterial puncture while effecting a one time use sterile connection. The product is particularly useful in making a bloodless venipuncture for introducer needles, especially employing the Seldinger Technique. The product effects a fluid retaining puncture and functions as a hook-up product for epidural and other spinal procedures, and other procedures such as angiography and radiology where guide wire placement is required.

The invention further provides a product comprised of a hub, cannula and septum seal within the hub which can be used for other purposes. For example, a guide wire or stylet could be passed through the septum seal and through the cannula. Also, the product may be used with a needle whereby the needle may pierce through the septum need from tie-to-time to infuse fluid into a front vessel of a patient. Upon withdrawal of the needle, the septum seal would again seal off the cannula from an outside environment.

What is claimed is:

1. A bloodless catheter comprising

a first hub having a bore at a proximal end;

a cannula fixed in and extending from an opposite distal end of said hub for invasive positioning in a blood vessel; and

a septum seal mounted in said bore of said hub in circumferentially sealed relation to prevent a flow of fluid from said cannula to said proximal end of said hub, said seal having a weakened central section.

2. A bloodless catheter as set forth in claim **1** wherein said seal is made of elastomeric material.

3. A bloodless catheter as set forth in claim **1** wherein said weakened section of said seal has a slit therein to define a valve.

4. A bloodless catheter as set forth in claim **1** wherein said seal is slidably mounted in said bore.

5. A bloodless catheter as set forth in claim **1** wherein said seal is mounted at one end of said bore with a face thereof exposed for swabbing.

6. A bloodless catheter as set forth in claim **1** further comprising first means in said hub for forming a flow path through said weakened section of said seal in response to a relative movement between said means and said seal.

7. A bloodless catheter as set forth in claim **6** wherein said first means is a tube mounted in said weakened section of said seal and extending into said cannula.

8. A bloodless catheter as set forth in claim **7** wherein said seal has a tubular portion receiving said tube in stretch-fit manner and a centrally disposed slit.

9. A bloodless catheter as set forth in claim **7** which further comprises second means for moving said seal over said tube to cause said tube to pass through said weakened section of said seal.

10. A bloodless catheter as set forth in claim **6** wherein said first means is a piercing ring mounted on said seal for pushing through said weakened section of said seal in a direction towards said cannula to define a flow path through said seal.

11. A bloodless catheter as set forth in claim **10** which further comprises second means for moving said piercing ring through said weakened section of said seal.

12. A bloodless catheter as set forth in claim **11** wherein said second means is a male luer adaptor slidably mounted in said bore of said hub in sealed relation and engaging said ring to push said ring through said weakened section of said seal.

13. A bloodless catheter as set forth in claim **6** which further comprises second means for moving said first means relative to said seal.

14. A bloodless catheter as set forth in claim **13** wherein said second means is a male luer adaptor slidably mounted in said bore of said hub in sealed relation and engaging said septum seal in sealed relation.

15. A bloodless catheter as set forth in claim **1** which further comprises

a needle hub telescopically mounted in said bore of said first hub; and an introducer needle fixed in said needle hub and extending through said seal in sealed relation and through said cannula.

16. A bloodless catheter as set forth in claim **1** which further comprises a guide wire extending through said weakened section of said seal and said cannula.

17. A bloodless catheter as set forth in claim **1** which further comprises a stylet extending through said weakened section of said seal and said cannula.

18. A bloodless catheter as set forth in claim **1** wherein said cannula is a needle with a sharpened tip.

19. In combination

first hub having a bore at a proximal end, a cannula fixed in and extending from an opposite distal end of said hub, a septum seal mounted in said bore of said hub in circumferentially sealed relation to prevent a flow of fluid from said cannula to said proximal end of said hub, and a tube mounted in said seal in sealed relation and extending into said cannula;

a needle hub telescopically mounted in said bore of said first hub and an introducer needle fixed in said needle hub and extending through said seal in sealed relation and through said cannula; and

a male luer adaptor for slidable mounting in said bore of said first hub after withdrawal of said needle hub therefrom, said adaptor being sized to engage and push said seal over said tube while receiving said tube therein in concentric relation.

20. In combination

a first hub having a bore at a proximal end, a cannula fixed in and extending from an opposite distal end of said hub, a septum seal mounted in said bore of said hub in circumferentially sealed relation, said seal having a centrally disposed slit to define a valve, and a piercing ring mounted on said seal concentrically of said slit;

a needle hub telescopically mounted in said bore of said first hub and an introducer needle fixed in said needle hub and extending through said seal in sealed relation and through said cannula; and

a male luer adaptor for slidable mounting in said bore of said first hub after withdrawal of said needle hub therefrom, said adaptor being sized to engage and push said piercing ring through said slit in said seal to communicate said adaptor with said cannula.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,699,221 B2
DATED : March 2, 2004
INVENTOR(S) : Vincent L. Vaillancourt

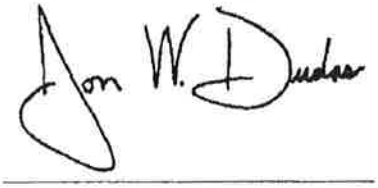
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3,
Lines 29 to 30, delete "to tube 15 seal (interference fit)".
Line 33, after "positioned" insert -- and --.

Column 7,
Line 28, delete "need".
Line 29, change "front" to -- blood --.

Signed and Sealed this

Fifteenth Day of June, 2004



JON W. DUDAS
Acting Director of the United States Patent and Trademark Office